J33015EN

User Defined Assay (UDA) Guide

VITROS® 5600 Integrated System

Ortho Clinical Diagnostics

VITROS®

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Revision History: User Defined Assay (UDA) Guide

Title	Location	Change
Worksheet Key	• On the System: Worksheet Key (page 8-3) • On the CD-ROM: Chapter 8, User Defined Assay Worksheet	Updated UD10 to UD20.

Note: Refer to V-Docs for Revision Histories of previous versions.

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Contents

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Chapter 1 Introduction

The User Defined Assay (UDA) feature allows you to expand the assay menu beyond those assays currently available from Ortho Clinical Diagnostics (OCD). Using the UDA feature, you can program assay protocols using pre-formatted assay templates and reagents from other vendors, or you can define your own protocols.
UDAs use the VITROS® MicroTip™ assay processing side of the MicroImmunoassay Center. This processing center is equipped with a thermally controlled reagent supply for on-system reagent storage (at 8°C ± 2°C), a metering system capable of delivering precise and accurate sample and reagent volume, an incubator (at 37°C), and a photometer with 12 wavelengths. The system supports enzymatic, colorimetric, and turbidimetric assay methodologies. You can use serum, plasma, urine, cerebrospinal fluid, and whole blood hemolysate samples. Sample dilution and pre-dilution are supported for these sample types. OCD provides empty reagent packs to be filled with your reagents.
Multiple calibration models (linear regression, cubic spline, Logit/Log4 and Logit/Log5) are available. The UDA feature is supported by all of the current capabilities of the system that ensure quality results for assays, including:

- Sample clot detection
- Sample indices checks
- Calibration checks: replicate range, monotonicity, variability of response
- Optical quality of reaction cuvettes
- Antigen excess/substrate depletion checks

This guide contains the following sections:

Disclaimer

WARNING: Ortho Clinical Diagnostics expressly disclaims all warranties with respect to user defined methods whether express or implied, including warranties of merchantability or fitness for a particular purpose.

WARNING: Since Ortho Clinical Diagnostics does not manufacture or otherwise control the reagents that may be used in the VITROS UD Pack, the warranty for the system does not extend to the performance of user-defined reagents (including user-defined test results or standard system test results that are affected by user-defined testing), their effect on the system operation and types and frequency of maintenance, or their effect on operator safety. The user assumes full responsibility for the selection of the proper reagents and entering the proper test parameters, use of the proper test protocol, correctness of the test results, and any associated errors or omissions. Each laboratory must establish its own performance characteristics in compliance with applicable laws and regulations before performing tests and reporting patient results for diagnostic purposes. The user assumes full responsibility for any local or regional regulatory requirements resulting from the use of user-defined reagents on the system.

WARNING: All fluids used on the system are disposed of in an on-board waste container. Use of reactive chemicals may create a hazard to the operator.

IMPORTANT: Neither the Customer nor its employees or agents may alter or modify any part of the Equipment or related software without prior written consent from Ortho-Clinical Diagnostics, Inc.

IMPORTANT: Report all VITROS® System errors generated when processing Research Use Only (RUO) Reagents to Customer Technical Services at Ortho Clinical Diagnostics.

VITROS MicroTip Assay Processing

The VITROS 5600 Integrated System can process discrete photometric assays and perform automatic dilutions using an aliquot of sample from primary collection tubes.
In the VITROS MicroTip assay processing side of the MicroImmunoassay Center, dispensed volumes of liquid reagent and sample are mixed in a cuvette and incubated for a specified time interval. A second reagent, if required, is added, and absorbance measurements are performed at preselected time intervals. The absorbance measurement is converted to concentration by an appropriate math model and associated calibration. Data is processed using a user-selected algorithm.
Refer to the following table for an example of MicroTip processing:

MicroImmunoassay Metering picks up VITROS VersaTip	
Reagent Supply rotates to position the appropriate reagent/diluent in the metering path	
MicroImmunoassay Metering aspirates R1 from the Reagent Supply	
↓	← A Cuvette Row is moved to the metering path for fluid mixing
MicroImmunoassay Metering dispenses R1 fluid into Cuvette	
MicroImmunoassay Metering seals and discards VITROS VersaTip and picks up FS MicroTip	
↓	← Aliquotted Sample in CuveTip is positioned for metering by the MicroSensor Subsystem
MicroImmunoassay Metering aspirates Samples from CuveTip	
↓	
MicroImmunoassay Metering dispenses Sample into Cuvette and performs mixing	→ MicroImmunoassay Metering seals and discards FS MicroTip
↓	
Cuvette incubated to preheat mixture	

(Continued)

MicroImmunoassay Metering picks up FS MicroTip or Vitros VersaTip

Reagent Supply rotates to position the appropriate reagent/diluent in the metering path

MicroImmunoassay Metering aspirates R2 from the Reagent Supply

MicroImmunoassay Metering dispenses R2 fluid into Cuvette and performs mixing

MicroImmunoassay Metering seals and discards Tip

Cuvette is incubated until read is required

Cuvette arm moves incubated Cuvette to read position

Cuvette is read and results are calculated

Photometer positions filter for read

After Cuvette is read unused cells may be used for additional tests or sent to waste if all cells are used

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Chapter 2 Define a User Defined Assay

Touch the steps below to access information about the procedure.

Step 1: Complete the User Defined Assay Worksheet

Special requirements: Use the vendor-supplied application sheet or your own assay protocol information to complete the User Defined Assay Worksheet.

1 Use the UDA Worksheet (page 8-1) to organize and record data about your user-defined assay.

2 Use the UDA Worksheet Key (page 8-3) to understand information on the UDA Worksheet.

Step 2: Define a New Assay

Special requirements: **Note:** Define the Sample Indices Threshold limits. Please refer to the V-Docs Reference Guide for more information.

1 Navigate to the Options & Configuration – User Defined Assays screen.

a Touch **Options** on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch **Configure Assays**.

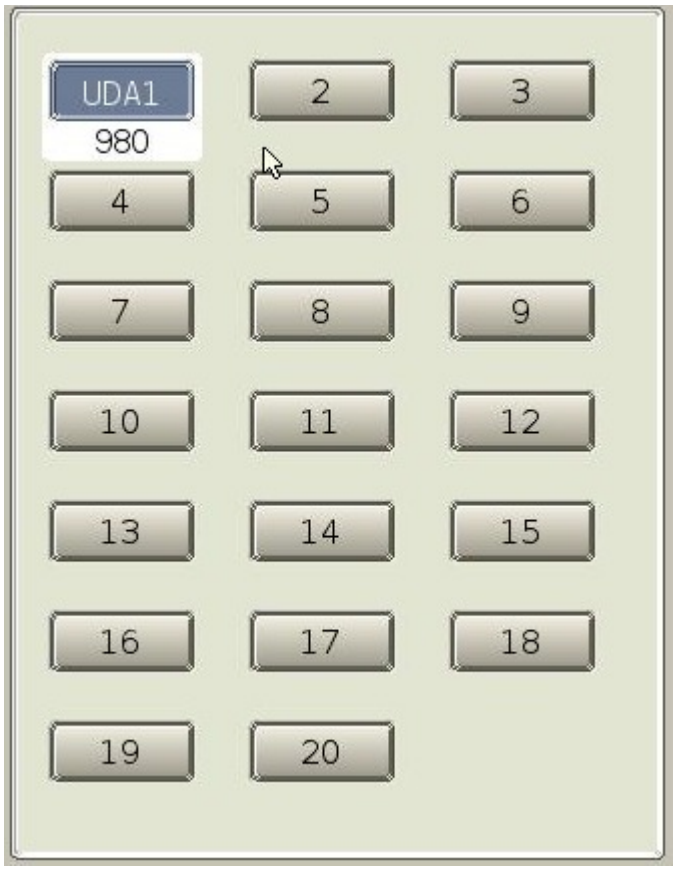
This button displays the Options & Configuration – Configure Assays screen.

c On the Options & Configuration – Configure Assays screen, touch the **User Defined Assays** process button.

This button displays a Warning dialog and the Options & Configuration – User Defined Assays screen.

d Read the information on the Warning dialog and touch OK to indicate that you accept responsibility for using non-OCD reagents on the system.

2 On the Options & Configuration – User Defined Assays screen, touch one of the 20 assay buttons to begin defining a UDA.



Note: By default, the user-defined assay buttons are named "1" through "20." The number below the button is the assay identification number that may be uploaded to the Laboratory Information System (LIS). LIS codes ranges from 980 to 999.

3 Touch the **New** process button.

4 Type a **Full Assay Name** (max. 20 characters).

This name displays on the Patient Report.

Note: The UDA name can have a maximum of 20 characters with no restrictions.

5 Type a **Short Assay Name** (max. 5 characters) for the new UDA.

The short name is used to identify this assay throughout the system.

IMPORTANT: The short assay name must be distinct from existing OCD or other user-defined assay short names. The system checks for assays that are supported by OCD or already defined assays.

6 Select a fluid from **Fluid Type** pulldown.

IMPORTANT: Serum is currently the only available option.

7 Select an assay model from the **Assay Model Type** pulldown.

The assay model type specifies when and how many photometric readings are taken. Your selection is used to populate the list of templates available in the next step. Available options are:

Assay Model Type	Description
None	Select this option if you are unsure of the assay model and would like to view all of the available templates in the next step.
2 Point Rate	The system takes two readings, one at the beginning of the reaction, and one at the end of the reaction.
2 Point w/ Antigen Excess Check	A two-point rate with an additional early read to check for Antigen Excess.
End Point	The system take a single reading at the end of the reaction and incubation period, with an optional blank.
Multi-point	The system takes a number of user-definable reads during the reaction, with an optional Antigen Excess check.

8 Select a protocol from the **Template** pulldown.

The protocol template is a set of default values for an assay model type and protocol. Templates are loaded onto your system through the Assay Data Disk (ADD). Any previously defined UDA also displays as a template. This allows you to define a new user defined assay using the specific information from an existing UDA as a starting point.

IMPORTANT: If appropriate, select the template options for End Point, Two Point Rate and Two Point Rate with Antigen Excess Rate Check that begin with an asterisk. These templates have pre-selected reagent and sample times that provide higher system throughput when multiple MicroTip assays are being run at the same time, compared to other templates. Use of the other templates could slow system throughput under times of high usage.

Template Name	Assay Model	Protocol Steps
*EPT1 R1-S-R2	End Point	• 1st Reagent Addition • Sample Addition • Optional Blank Read • 2nd Reagent Addition • End Point Read

(Continued)

*2PTAE R1-S-R2	Two Point Rate with Antigen Excess Rate Check	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • Early Rate Read • 1st Rate Read • 2nd Rate Read
*2PT R1-S-R2	Two Point Rate	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • 1st Rate Read • 2nd Rate Read

Template Name	**Assay Model**	**Protocol Steps**
EPT1 R1-S	End Point	• Reagent Addition • Optional Blank Read • Sample Addition • End Point Read
EPT1 R1-R2-S	End Point	• 1st Reagent Addition • 2nd Reagent Addition • Optional Blank Read • Sample Addition • End Point Read
EPT2 R1-S	End Point	• Reagent Addition • Sample Addition • Optional Blank Read • End Point Read
EPT2 R1-S-R2	End Point	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • Optional Blank Read • End Point Read
EPT2 R1-R2-S	End Point	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • Optional Blank Read • End Point Read

(Continued)

2PTAE R1-S	Two Point Rate with Antigen Excess Rate Check	• Reagent Addition • Sample Addition • Early Rate Read • 1st Rate Read • 2nd Rate Read
2PTAE R1-R2-S	Two Point Rate with Antigen Excess Rate Check	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • Early Rate Read • 1st Rate Read • 2nd Rate Read
2PT R1-S	Two Point Rate	• Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read
2PT R1-R2-S	Two Point Rate	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read
NPT R1-S	Multiple Point Rate	• Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read ... • 12th Rate Read
NPT R1-S-R2	Multiple Point Rate	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • 1st Rate Read • 2nd Rate Read ... • 12th Rate Read

(Continued)

NPT R1-R2-S	Multiple Point Rate	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read ... • 12th Rate Read

9 Select a calibration model type from the **Cal Model Type** pulldown.

You can select up to six calibration levels for each UDA, and can program and store the concentration levels for each calibrator.

Available calibration models include:

- Logit/Log4 (5-6 calibrator levels)
- Linear (2-6 calibrator levels)
- Logit/Log5 (6 calibrator levels)
- Cubic Spline (4-6 calibrator levels)

10 Type the number of calibrator bottles (levels) (1-6) used for this assay.

11 Type the number of replicates (1-40) for each calibrator level required for the assay calibration.

12 Touch the **Save** process button.

Note: Once a UDA is configured and saved, it is available for use in any capacity on the system. UDA's, once programmed, are included as part of a normal system backup.

13 Select the UDA saved in the previous step.

14 Touch the **Review/Edit Assay** process button.

This button displays the first of three Options & Configuration – Review/Edit Assay screens.

These screens show details for the UDA based on the calibration model type, assay model type, and template selected.

15 Touch the **View More Parms** process button to view and cycle through all of the available screens.

Step 3: Configure Dilution Parameters

Special requirements:

1 Touch the **Dilution Parms** process button on the bottom of the Options & Configuration – Review/Edit Assay screen.

This button displays the Edit Dilution Parameters dialog box.

Note: For a user-defined diluent to appear on the drop-down list, you must first define it. See Define a New User Diluent (page 3-5) for more information.

WARNING: If changing an existing UDA diluent or dilution factor, consider recalibration of the assay.

2 Select a diluent from the available options on the Edit Dilution Parameters dialog box.

Diluents are loaded onto your system through the ADD and any previously user-defined diluents display as available selections.

Available diluents are:

- Saline
- BSA
- Water
- Specialty
- UED
- ApoDiluent
- DATDil2
- DATDil
- Lysis Buff
- User Defined Diluents

3 Type a new value for the **Standard Dilution Factor**.

This is the value used to calculate a result when a sample is diluted with a diluent prior to analysis. Supported dilution factors are 1, 1.3-101, where 1 is an undiluted sample.

For example, a standard dilution factor of 5 is 1 part sample and 4 parts diluent.

4 If you wish to enable reflex dilution, touch On.

Reflex dilution enables the system to automatically dilute and re-assay samples with out-of-range results.

5 Type a reflex **Dilution Factor**.

This reflex dilution factor will be used for samples requiring dilution at a reflex metering station.

6 Type a **Reduction Factor**.

The reduction factor is used to reflex test results that are below the reportable range. The standard dilution factor is multiplied by the reduction factor (valid entries 0.2-1.0). The resulting reflex dilution will be less than the standard dilution factor but must still be greater than 1.3.

Standard Dilution Factor × Reduction Factor = Dilution Factor for Reflex Test

Note: This is only applicable if the protocol includes pre-dilution of sample. The reduction factor will allow a smaller pre-dilution factor.

7 Touch Save.

Step 4: Configure Result Parameters

Special requirements:

1 Touch the **Result Parms** process button on the bottom of the Options & Configuration – Review/Edit Assay screen.

This button launches the Options & Configuration – Edit Results Parameters screen.

2 Select a Reporting Type

a **Quantitative** — Reference, Supplementary, and Measuring (Reportable) Ranges

b **Qualitative** — 2 to 5 Qualitative Range and Measuring (Reportable) Range

Choice will determine what information is needed in step Step 10 (page 2-8) below.

3 In the **RESULT PARAMETERS** section of the screen, touch the **Units** pulldown and select a unit type from the list, or type the units into the box (max. 8 characters).

WARNING: Changing units of an existing UDA affects previous results. Previous results in the old units are not converted and no longer display correctly.

4 Enter the number of **Significant Digits**.

Significant digits are the maximum number of digits (1–6) that display for all results and numerical data.

5 Enter the number of **Precision Digits**.

Precision digits are the maximum number of digits (0–3) that display to the right of the decimal point.

6 In the **USER ADJUSTED PARAMETERS** section of the screen, type the **Slope** necessary to correlate to the comparative method.

7 Type the **Intercept** necessary to correlate to a comparative method.

The intercept is the mathematically established value of the observed result for method ‘y’ when the result determined by method ‘x’ equals zero. The intercept value may be negative or positive.

8 Select a time from the **CuveTip Expiration Time** pulldown.

This is the amount of time a CuveTip sample can remain in the CUVETIP RING for this particular User Defined Assay before it is flagged as expired. Default is 35 minutes and minimum is 5 minutes.

You can determine this number by considering the following factors: the approximate amount of time that a small amount of your sample can remain stable, considering sample volatility and the affects of temperature and humidity on the sample’s stability.

When you set a shorter expiration time, you affect the priority of processing of this sample within the system. However, if the system is very busy or other tasks are queued as stat, you risk the possibility that your sample will be flagged by the system as expired before it can be processed.

9 Touch the **Temperature Sensitive** check box, if required.

The temperature sensitive assays option improves the precision of temperature sensitive assays by restricting the cells within a cuvette row that can be used. Although precision may be improved, throughput may be reduced.

10 In the **RANGES** section of the screen enter the Quantitative or Qualitative Range information depending on the choice made in step Step 2 (page 2-8) above.

a Quantitative Ranges

Quantitative Ranges	Description
Type the upper and lower values for the **Reference** range.	The reference range defines the highest and lowest amounts of the analyte found in an apparently healthy population. Also referred to as “normal range.”

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Type the upper and lower values for the **Supplementary** range.	The supplementary range is the operator-defined limits, outside or equal to the reference range, for results that may require immediate attention and/or action by the laboratory.
Type the upper and lower values for the **Measuring (Reportable)** range.	The lowest to the highest analyte concentration that the protocol is capable of predicting. Also referred to as *linear range* or *dynamic range*.

b Qualitative Ranges

Qualitative Ranges	Description
Type the **Number of Qualitative Ranges** (2–5).	This value indicates how many rows of result text and cut-off values are displayed in the **RANGES** section of the screen.
Type the result text for each qualitative range.	Qualitative result string for each range
Type the cut-off values for each qualitative range	Range of results that will report the defined qualitative result string.
Report Qualitative Result Outside of Range	If selected, the qualitative result string will be reported if the result is outside of the measuring (reportable) range.
Type the upper and lower values for the **Measuring (Reportable)** range.	The measuring (reportable) range defines the lowest and the highest amount of the analyte that an assay protocol is capable of predicting. Also referred to as the “calibration range” or “linear range.”

11 Touch the **Save** process button.

12 Touch the More Assay Parms process button to configure additional parameters.

The Additional Parameters dialog that displays depends on the selected assay's model type:

- End Point (page 2-9)
- 2 Point Rate (page 2-10)
- 2 Point with Antigen Excess Rate Check (page 2-11)
- Multi Point (page 2-12)

End Point

Special requirements: If you previously selected End Point as the assay model type, the Edit End Point Additional Parameters dialog displays when you touch the **More Assay Parms** process button. 

1 Edit the following parameters for this assay:

Initial Absorbance Limits	The range of values expected at the system's first check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3
Blank Absorbance Limits	The range of values expected at the system's blank-read check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3

2 Touch Save to save the result parameters and return to the Options & Configurations – Edit Results Parameters screen.

2 Point Rate

Special requirements: If you previously selected 2 Point Rate as the assay model type, the Edit 2 Point Rate Additional Parameters dialog displays when you touch the **More Assay Parms** process button. 

1 Edit the following parameters for this assay:

Initial Absorbance Limits	The range of values expected at the system's first check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3
Second Absorbance Limits	The range of values expected at the system's second check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3

Antigen Excess Factor	An absorbance value that, when added to the high calibrator absorbance value, will set the antigen excess limit. For example, if the absorbance of multiple runs of the high level calibrator is 0.900 and the operator decides to use a 20% cutoff, the operator will enter a value of 0.18 (20% of 0.900) absorbance units. • Values are 0-10 • Field length including the decimal point: 7 characters • Precision after decimal point: 4 digits **IMPORTANT:** Before changing the default Antigen Excess Factor, for your UDA, please review Antigen Excess (page 4-1).

2 Touch Save to save the result parameters and return to the Options & Configurations – Edit Results Parameters screen.

2 Point with Antigen Excess Rate Check

Special requirements: If 2 Point with Antigen Excess Rate Check is selected as the assay model type, the Edit 2 Point with Antigen Excess Rate Check Additional Parameters dialog is displayed when you touch the **More Assay Parms** process button. 

1 Edit the additional parameters for this assay.

Initial Absorbance Limits	The range of values expected at the system's first check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3
Second Absorbance Limits	The range of values expected at the system's second check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3
Antigen Excess Factor	An absorbance value that, when added to the high calibrator absorbance value, will set the antigen excess limit. For example, if the absorbance of multiple runs of the high level calibrator is 0.900 and the operator decides to use a 20% cutoff, the operator will enter a value of 0.18 (20% of 0.900) absorbance units. • Values are 0-10 • Field length including the decimal point: 7 characters • Precision after decimal point: 4 digits **IMPORTANT:** Before changing the default Antigen Excess Factor, for your UDA, please review Antigen Excess (page 4-1).

Early Rate Read Index	The earliest-read value that is not included in the response computation. • Values are 1 or 2 • Field length: 1 character **Note:** This value is not displayed for 2–Point assays without antigen excess rate check.

2 Touch Save to save the result parameters and return to the Options & Configurations – Edit Results Parameters screen.

Multi-Point Rate

Special requirements: If Multi Point is selected as the assay model type, the Edit Multi-Point Rate Additional Parameters dialog is displayed when you touch the **More Assay Parms** process button. 

1 Edit the additional parameters for this assay.

Initial Absorbance Limits	The range of values expected at the system's first check of the calibration curve to determine whether it is within the expected assay range. Absorbance units. • Values for each field are -0.2 to 3.5 • Field length (including sign): 6 characters • Significant digits: 4 • Precision digits: 3
Antigen Excess Limit	A slope that defines antigen excess. Samples with slopes above the Antigen Excess Limit are "flagged" as being in antigen excess. For example, if the slope of the calibrator is 1.0 and the user decides to use a 20% cutoff, a slope of 1.20 is entered as the Antigen Excess Limit. A sample giving a slope of 1.25 will be in antigen excess (1.25 > 1.20). Response units. • Values are 0-10 • Field length including the decimal: 7 characters • Precision after decimal point: 4 digit
Nonlinearity Limit	The amount of curvature required prior to trimming the calibration curve. Response units. • Values are 0-1000 • Field length (including the decimal) 9 characters • Field length (including decimal): 9 characters • Precision after Decimal Point: 4 digits

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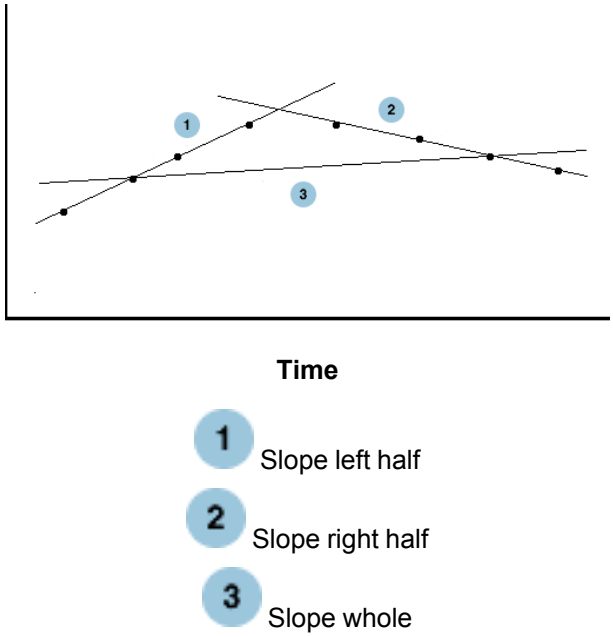

Increasing Rate Flag	A check box that determines whether the assay has an increasing absorbance with time (checked) or a decreasing absorbance with time (unchecked). The default is checked. Touch the check box to remove the check mark and indicate that the assay has a decreasing absorbance with time.
Max Relative SD of Regression Line	The maximum noise allowed in a regression that can be used for a prediction (relative error). Absorbance units. • Values are 0-100 • Field length (Including decimal): 8 characters • Precision after decimal point: 4 digits Max Sy × *x* in absorbance units ÷ absorbance range **Note:** This is the maximum SD of residuals (relative to the absorbance range) of absorbances around a regression line through the kinetic curve allowed before trimming noisy points. Increasing the number will decease the number of noisy points removed. Decreasing this number will cause more points to be trimmed. Default values are set at the maximum level and essentially turnoff spike detection.
Minimum Read Points Allowed	The minimum number of points required in regression after trimming or spike noise reduction to allow a response to be generated. • Values are 2-12 • Field length: 2 characters **Note:** This is the minimum number of kinetic points remaining, after trimming, needed to compute a response. If there are fewer than the Min Read Points Allowed after trimming out noisy points the replicate is rejected.

Max SD of Regression Line	The maximum noise allowed in a regression that can be used for a prediction (absolute error). Absorbance units. • Values are 0-10 • Field length (including decimal): 7 characters • Precision after decimal point: 4 digits Max Sy × *x* in absorbance units **Note:** This is the maximum SD of residuals of absorbances around a regression line through the kinetic curve allowed before trimming noisy points. Increasing the number will decrease the number of noisy points removed. Decreasing this number will cause more points to be trimmed. Default values are set at the maximum level and essentially turn-off spike detection.

2 Touch Save to save the result parameters and return to the Options & Configurations – Edit Results Parameters screen.

IMPORTANT: Multi-point assay selection will decrease the throughput of all assays.

Step 5: Configure Protocol Parameters

Special requirements: **Note:** The protocol parameters that are configured in this step are dependent upon the template selected. Use of templates starting with an astrisk have pre-selected reagent and sample times that provide higher system throughput when multiple MicroTip assays are being run at the same time, compared to other templates.

1 Touch the **Protocol Parms** process button at the bottom of the Review/Edit Assay screen.

This button launches the Options & Configuration – Edit Protocol Parameters screen.

The left side of the Options & Configuration – Edit Protocol Parameters screen displays the **Protocol Steps** (determined by the template chosen).

The right side of the Options & Configuration – Edit Protocol Parameters screen displays the **View Protocol** parameters for each protocol step.

2 On the left side of the Options & Configuration – Edit Protocol Parameters screen, touch one of the **Protocol Steps** (Reagent, Sample, Incubation, Read) in the list to display the selected Protocol Step dialog.

3 Touch the View Protocol process button to re-display the **View Protocol** parameters for each protocol step on the right side of the screen.

This button re-displays the **View Protocol** parameters.

The following steps describe how to configure each protocol parameter.

4 Touch a **Reagent** protocol step displayed on the left side of the screen to display the protocol step dialog.

a Type the reagent **Volume (µL)** (30 – 200µL in 0.1µL increments) in the text box.

This volume is only applicable to the first reagent addition.

b Select a **Pack Name/Bottle** designation from the pulldown.

5 Touch a **Sample** protocol step displayed on the left side of the screen to display the protocol step dialog.

   a Type the sample **Volume (µL)** (2 – 59.9µL in 0.1µL increments) in the text box.

   Note: For samples that require pre-dilution (standard dilution), enter the volume of the diluted sample (sample plus diluent).

6 Touch an **Incubation** protocol step displayed on the left side of the screen to display the protocol step dialog.

   a Select an incubation time from the **Seconds** pulldown.

   Note: If an Incubation Protocol Step is not needed, select 0 (zero) or the shortest available time displayed to work within the system timing cycle.

7 Touch a **Read** protocol step displayed on the left side of the screen to display the protocol step dialog.

   a Select a **Wavelength** from the pulldown or select "None" to disable the read protocol step.

8 When you finish configuring the protocol data, touch the Save button.

9 Touch the **Print Protocol** button to print the displayed protocol information.

Step 6: Configure Calibration Parameters

Special requirements: **Note:** If your UDA uses a factor that is based on the Molar Extinction Coefficient, please skip this step and Refer to Molar Extinction Coefficient (page 6-1).

1 Touch the **Calibration Parms** process button at the bottom of the Review/Edit Assay screen.

This button launches the Enter/Edit Calibration Parameters screen.

2 On the Enter/Edit Calibration Parameters screen, touch the **Lot** pulldown menu and select a calibrator lot number from the list or type a new lot number in the box (max. 2 digits).

3 Type a **Calibrator Value** for each calibrator bottle for the lot you selected.

The calibrator value is the known amount of analyte contained in the calibrator (1–5 characters including sign and decimal point, numeric).

4 (Optional) For a new lot, enter the Expiration Date using the current date format. (If previously entered, the Expiration Date for an existing lot is displayed in the Expiration Date field.)

5 Type new **Dilution Factor** values for each bottle if the calibrator requires dilutions prior to processing.

The dilution factor is the automatic dilution factor for the assay to be calibrated (1 – 4 characters, including decimal point).

Note: The limits on the factor are 1, 1.3-101 and no less than tenths.

6 Type new **Calibrator Replicate Response Range** values for each bottle.

This range is the maximum allowable difference between replicates of the same calibrator. Values are 0 to 0.2.

7 Touch Save to save the calibration parameters.

8 Touch the More Cal Parms process button to configure additional Calibration parameters for the assay.

Note: The dialog that displays to configure additional calibration parameters depends on the selected assay's calibration model: Linear, Logit/Log, and Cubic Spline.

a If Linear or Logit/Log is the selected assay's calibration model type, edit the Linear or Logit/Log Parameters (page 2-16).

b If Cubic Spline is the selected assay's calibration model type, edit the Cubic Spline Additional Parameters (page 2-17).

Linear or Logit/Log Parameters

Special requirements: If Linear or Logit/Log is the selected assay's calibration model type, the Edit Linear or Logit/Log Additional Parameters dialog is displayed when you touch the **More Cal Parms** process button.

1 Edit the following parameters for this assay:

Monotonicity	A choice of Increase Monotinicity or Decrease Monotinicity. This indicates whether the calibration uses increasing or decreasing monotonicity.
Max Response High	The maximum high calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Max Response Low	The maximum low calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Cal fit Goodness Limit	(R^2 Correlation Coefficient) The measure of fit of the data points generated by the assay to the calibration model. Values are 0.000 to 1.000 with a maximum of 5 characters including the decimal point. **Note:** A value of 1.000 allows only a perfectly fit cal curve to be accepted. Anything smaller is less restrictive.
Min Response High	The minimum high calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Min Response Low	The minimum low calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Calibration Interval (days)	The number of days between calibrations. Values are 1-999.

Note: Consider the following guidelines:

- If the lowest response from a calibration is less than the Min Response Low or greater than the Min Response High, the calibration is rejected.
- If the highest response from a calibration is less than the Max Response Low or greater than the Max Response High, the calibration is rejected.
- You can widen the acceptance range for lowest response (by increasing difference between Min Response High and Min Response Low) to decrease the chance of rejecting a calibration.
- You can also widen the acceptance range for highest response (by increasing the difference between Max Response High and Max Response Low).
- At the start of optimization these values may be maxed out to response defaults of -3.0 to 3.0 OD and then tightened as you add response checks to the UDA calibration. The defaults make this check inoperative.

2 Touch Save to save the parameters and return to the Options & Configuration – Enter/Edit Results Parameters screen.

3 Touch Return/Cancel to continue and return to the Options & Configuration – Review/Edit Assay screen.

Cubic Spline Additional Parameters

Special requirements: If Cubic Spline is selected as the cal model type, the Edit Cubic Spline Additional Parameters dialog is displayed when you touch the **More Cal Parms** process button.

1 Edit the following parameters for this assay:

Monotonicity	A choice of Increase Monotinicity or Decrease Monotinicity. This indicates whether the calibration uses increasing or decreasing monotonicity.
Max Response High	The maximum high calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Max Response Low	The maximum low calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Min Response High	The minimum high calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Min Response Low	The minimum low calibration response. Values are -1000 to 1000 with a maximum of 8 characters including the decimal point and minus sign. Response units.
Calibration Interval (days)	The number of days between calibrations. Values are 1-999.

Note: Consider the following guidelines:

- If the lowest response from a calibration is less than the Min Response Low or greater than the Min Response High, the calibration is rejected.
- If the highest response from a calibration is less than the Max Response Low or greater than the Max Response High, the calibration is rejected.
- You can widen the acceptance range for lowest response (by increasing difference between Min Response High and Min Response Low) to decrease the chance of rejecting a calibration.
- You can also widen the acceptance range for highest response (by increasing the difference between Max Response High and Max Response Low).
- At the start of optimization these values may be maxed out to response defaults of -3.0 to 3.0 OD and then tightened as you add response checks to the UDA calibration. The defaults make this check inoperative.

2 Touch Save to save the parameters and return to the Options & Configuration – Enter/Edit Results Parameters screen.

3 Touch Return/Cancel to continue and return to the Options & Configuration – Review/Edit Assay screen.

Step 7: Configure Triple Read Parameters

IMPORTANT: Before changing the default triple read parameters for your UDA, please review the Triple Read (page 5-1) section of this UDA Guide.

1 If changing Triple Read parameters is required, touch the **Triple Read Parms** process button at the bottom of the Options & Configuration Review/Edit Assay screen.

This button launches the Edit Triple Read Parameters dialog box.

Note: The Measuring (Reportable) Min and Measuring (Reportable) Max are the reportable range of values you entered for this UDA on the Options & Configuration Edit Result Parameters screen.

2 Type the **Critical Concentration**.

The default is the mid point between the Measuring (Reportable) Min and Measuring (Reportable) Max.

3 Type the **Triple Read Limit** for the Measuring (Reportable) Min value.

If you change this value it must be greater than 0.

4 Type the Triple Read % Limit for the Critical Concentration.

5 Type the Triple Read % Limit for the Measuring (Reportable) Max.

6 Touch Save.

WARNING: Larger Triple Read Limits can degrade precision while a lower limit can improve precision but can suppress potentially good results. The goal is to set the appropriate balance between these two factors.

Step 8: Enter Reagent Lot Information

Reagent Lot information is used to track the on board stability and shelf expiration for a reagent. This information can be accessed by touching the **Reagent Lot** process button at the bottom of the Options & Configuration Review/Edit Assay screen.

1 Touch the **Reagent Lot** process button at the bottom of the Options & Configuration Review/Edit Assay screen.

This button launches the Reagent Lot Information dialog box.

2 Type the **On Board Stability**, in days (1-99), for the reagent.

Reagents that are on board for longer than the specified period are flagged on the Reagent Management screen and on the Results report.

Note: Any change to the on board stability for an existing reagent is automatically calculated for any packs of that reagent currently on board.

3 Type the **Reagent Lot Number**, up to 12 characters.

Note: The user-defined Reagent Lot Number and the reagent pack lot number are both included on the Calibration Report and uploaded to the LIS (if Upload Extended Result Data is selected on the Options & Configuration – Configure LIS screen). When reviewing the Options & Configuration – Review/Edit Calibrations, or Reagent Management screens, the lot number displayed is the reagent pack lot number assigned by Ortho Clinical Diagnostics.

Note: If you change the lot number, you should consider a recalibration of the UDA.

4 Type the **Shelf Expiration Date** of the reagent.

Expired reagents are flagged on the **Reagent Management** screen and on the Results report.

Note: Any change to the shelf expiration date for an existing reagent is not reflected until a new pack of that reagent is loaded.

5 Touch Save.

Note: All reagent packs used by this assay are updated with this information.

WARNING: Tests have shown that some reagents have lower on board stability at lower residual volumes in the pack. Manufacturers' test data may not be applicable to the system.

Step 9: Fill and Load Reagent Packs

Note: Reagent Lot information must be entered before a reagent can be loaded onto the system.

IMPORTANT: Be sure to follow these instructions whenever you fill Ortho Clinical Diagnostics reagent packs.

Caution: Do not use reagent packs that are damaged or that have any damaged packaging. Verify that labels and caps are secured. To avoid damage, be careful when opening the outer packaging with sharp instruments.

Caution: Use caution when considering reagents such as strong alkaline and acid solutions, organic solvents, viscous liquids, heavy metals, metal chelating agents, bleach, or ammonia. These materials may have adverse effects on the system and may produce incorrect results for both OCD-supplied and User Defined Assays.

IMPORTANT: Do not reuse reagent packs.

Note: Reagent is assigned to a reagent pack and bottle on the Edit Protocol Parameters screen when a Reagent Protocol Step is selected.

1 Inspect the packaging for any signs of damage. Remove the reagent pack from the carton and ensure that the pack is not damaged. The label and cap should be securely attached.

2 Write any necessary information about the reagent on the label before you fill the pack.

3 Estimate the fill volumes for the reagent packs, based on the ratio of Reagent A to Reagent B. Refer to the UDA Guidelines for reagent volume ranges and dead volumes (page 7-1).

Note: An optional tray (catalog # 6802120) is available to hold reagent packs while you fill them.

4 Remove the cap from Bottle A. Keep the cap on Bottle B.

5 Ensure that there are no particulates in the reagent, and then transfer the reagent into Bottle A gently to prevent foaming or splashing.

6 Replace the cap on Bottle A. Tighten the cap until it is snug enough to protect the reagent and provide sufficient resistance for the MICROTIP PACK OPENER.

7 If Bottle B is being used, remove the cap from Bottle B.

8 Repeat step 5 and step 6 for Bottle B, if a second reagent is used.

9 After you fill both bottles, store the pack according to reagent instructions until you are ready to load it onto the system.

IMPORTANT: Do not loosen or remove the caps before you load the reagent pack.

10 Load the reagent pack. Please refer to V-Docs for more information on loading a reagent pack.

WARNING: High fluid heights can trigger false bubble detection codes.

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Chapter 3 Maintain a User Defined Assay

Perform the following procedures to review, configure, edit and delete a User Defined Assay.

Review/Edit a User Defined Assay

1 Navigate to the Options & Configuration – User Defined Assays screen.

a Touch **Options** on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch **Configure Assays**.

This button displays the Options & Configuration – Configure Assays screen.

c On the Options & Configuration – Configure Assays screen, touch the **User Defined Assays** process button.

This button displays a Warning dialog and the Options & Configuration – User Defined Assays screen.

d Read the information on the Warning dialog and touch OK to indicate that you accept responsibility for using non-OCD reagents on the system.

2 On the Options & Configuration – User Defined Assays screen, touch one of the 20 assay buttons to select the assay to review/edit.

3 Touch the **Review/Edit Assay** process button.

This button displays the first of three Options & Configuration – Review/Edit Assay screens.

These screens show details for the UDA based on the calibration model type, assay model type, and template selected.

4 Touch the **View More Parms** process button to view and cycle through all of the available screens.

Configure Sample Indices Threshold Limits

1 Navigate to the Options & Configuration – Configure Assays screen.

a Touch Options on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch Configure Assays.

This button displays the Options & Configuration – Configure Assays screen.

2 On the Options & Configuration – Configure Assays screen, touch the appropriate Body Fluid button and Assay button for the assay you wish to configure limits for, and then touch the Sample Indices Thresholds process button.

This button displays the Sample Indices Threshold Limits dialog box.

3 Touch the Enable Sample Indices Checks check box for to select it, if it is not already checked.

Default indices are set at the high end of the concentration values for each index.

4 Type new threshold values for **Hemolysis**, **Icterus**, and **Turbidity** in their text boxes.

Values above this threshold are flagged with the appropriate Sample Indices Flag (H, I, or T).

5 Touch Save.

Edit Reagent Lot Information

Reagent Lot information is used to track the on board stability and shelf expiration for a reagent. This information can be accessed by touching the **Reagent Lot** process button at the bottom of the Options & Configuration Review/Edit Assay screen.

IMPORTANT: If more than one user defined assay uses the same reagent, a change to the reagent lot information here applies to all UDAs that contain that reagent.

Note: Only one reagent lot can be on the system at a time. If the reagent lot on board changes, the on board packs are marked unusable and should be removed from the system.

1 Select the UDA that contains the reagent that you would like to edit.

Tell me how to Review/Edit a User Defined Assay (page 3-1).

2 Touch the **Reagent Lot** process button at the bottom of the Options & Configuration Review/Edit Assay screen.

This button launches the Reagent Lot Information dialog box.

3 Type the **On Board Stability**, in days (1-99), for the reagent.

Reagents that are on board for longer than the specified period are flagged on the Reagent Management screen and on the Results report.

Note: Any change to the on board stability for an existing reagent is automatically calculated for any packs of that reagent currently on board.

4 Type the **Reagent Lot Number**, up to 12 characters.

Note: The user-defined Reagent Lot Number and the reagent pack lot number are both included on the Calibration Report and uploaded to the LIS (if Upload Extended Result Data is selected on the Options & Configuration – Configure LIS screen). When reviewing the Options & Configuration – Review/Edit Calibrations, or Reagent Management screens, the lot number displayed is the reagent pack lot number assigned by Ortho Clinical Diagnostics.

Note: If you change the lot number, you should consider a recalibration of the UDA.

5 Type the **Shelf Expiration Date** of the reagent.

Expired reagents are flagged on the **Reagent Management** screen and on the Results report.

Note: Any change to the shelf expiration date for an existing reagent is not reflected until a new pack of that reagent is loaded.

6 Touch Save.

Delete a User Defined Assay

1 Navigate to the Options & Configuration – User Defined Assays screen.

a Touch **Options** on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch **Configure Assays**.

This button displays the Options & Configuration – Configure Assays screen.

c On the Options & Configuration – Configure Assays screen, touch the **User Defined Assays** process button.

This button displays a Warning dialog and the Options & Configuration – User Defined Assays screen.

d Read the information on the Warning dialog and touch OK to indicate that you accept responsibility for using non-OCD reagents on the system.

2 On the Options & Configuration – User Defined Assays screen, touch the UDA that you would like to delete.

3 Touch the **Delete** process button.

This button displays the Delete Assay dialog box.

4 Read the information on the Delete Assay dialog box and touch Yes to verify that you want to delete the assay and its associated records and information from the system.

5 Touch Yes to delete the assay and its result records, QC and calibration records, and to remove the assay from sample programs.

Delete a User Defined Calibrator Lot

1 Navigate to the Options & Configuration – User Defined Assays screen.

a Touch **Options** on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch **Configure Assays**.

This button displays the Options & Configuration – Configure Assays screen.

c On the Options & Configuration – Configure Assays screen, touch the **User Defined Assays** process button.

This button displays a Warning dialog and the Options & Configuration – User Defined Assays screen.

d Read the information on the Warning dialog and touch OK to indicate that you accept responsibility for using non-OCD reagents on the system.

2 Select the UDA that contains the user defined calibrator lot that you would like to delete.

Tell me how to Review/Edit a User Defined Assay (page 3-1).

3 Touch the **Calibration Parms** process button at the bottom of the Review/Edit Assay screen.

This button launches the Enter/Edit Calibration Parameters screen.

4 Select the lot to be deleted from the **Lot** pulldown.

5 Touch the **Delete Lot** process button.

This button displays the Delete Lot dialog box.

6 Touch Yes to delete the Calibration lot.

Define a New User Defined Diluent

1 Navigate to the Options & Configuration – User Defined Diluents screen.

a Touch **Options** on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch **Configure Assays**.

This button displays the Options & Configuration – Configure Assays screen.

c On the Options & Configuration – Configure Assays screen, touch the **User Defined Diluents** process button.

This button displays the Options & Configuration – User Defined Diluents screen.

2 On the Options & Configuration – User Defined Diluents screen, touch the **New** process button.

3 Type a name for the new diluent in the **Diluent Name** text box (max. 10 characters).

4 Select a pack and bottle designation for the new diluent from the **Pack Name/Bottle** pulldown.

Note: Two bottles in each of the two diluent packs let you define up to four diluents. Bottle A is the inner chamber and Bottle B is the outer chamber.

5 Type the **On Board Stability**, in days, for the diluent.

6 Type the **Diluent Lot Number**, up to 12 characters.

7 Type the **Shelf Expiration Date** of the diluent.

8 Touch the **Save** process button.

Delete a User Defined Diluent

1 Navigate to the Options & Configuration – User Defined Diluents screen.

a Touch **Options** on the Status Console.

This button displays the Options & Configuration screen.

b On the Options & Configuration screen, touch **Configure Assays**.

This button displays the Options & Configuration – Configure Assays screen.

c On the Options & Configuration – Configure Assays screen, touch the **User Defined Diluents** process button.

This button displays the Options & Configuration – User Defined Diluents screen.

2 Select the user defined diluent that you would like to delete.

3 Touch the **Delete** process button.

This button displays the Delete Diluent dialog box.

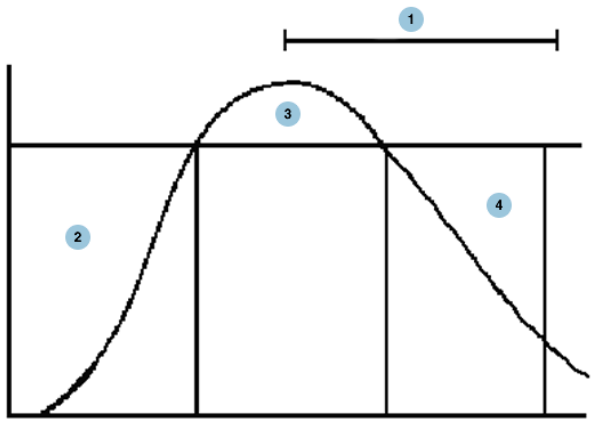
4 Touch Yes to delete the diluent.

Chapter 4 Antigen Excess

Antigen Excess Introduction

IMPORTANT: If a UDA method has the potential to encounter an antigen excess condition, it is recommended that the user define an appropriate method for detection of this condition by the system. This section is intended to provide guidance regarding the programmable options available for identification of an antigen excess condition. It is the user's responsibility to determine which option if any is best suited to a particular assay or method. For commercially available reagent kits other than those provided by Ortho Clinical Diagnostics, the reagent manufacturer should provide guidelines and recommendations on how to detect antigen excess.

Antigen Excess refers to the region of the assay dose response curve where analyte (antigen) concentration exceeds the effective antibody concentration in the reaction, inhibiting the agglutination reaction.



1 Antigen Excess

2 Result within measuring (reportable) range

3 Result above measuring (reportable) range

4 Antigen Excess Result at risk of being posted within the measuring (reportable) range

The UDA feature allows you to configure an assay so that Antigen Excess is detected. The system uses one of three methods to detect Antigen Excess:

- Early Absorbance Read
- Early Rate Read
- Antigen Excess Defined Kinetics Slope Changes

Method 1: Early Absorbance Read

The Antigen Excess flag is set at an absorbance level greater than the high calibrator absorbance when measured at the first read.

Note: With the Early Absorbance Read method for Antigen Excess detection, highly turbid samples may trigger false Antigen Excess flags. In these cases, it is recommended to use the Early Rate Read method for Antigen Excess detection.

Method 1: Early Absorbance Read (page 4-2)

Method 2: Early Rate Read

An additional absorbance reading is added to a 2-point rate assay, typically immediately after the last fluid addition step. This additional reading is used to take an early look at the reaction slope (change in optical absorbance per unit time) to determine if the observed slope is greater than a predetermined maximum slope limit.

Method 2: Early Rate Read (page 4-4)

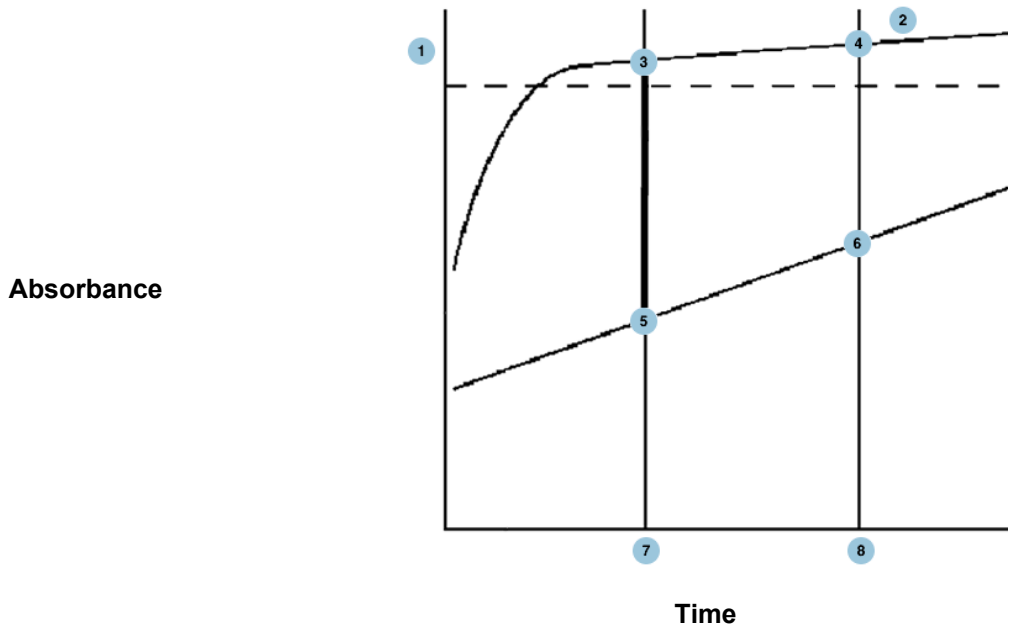
Method 3: Antigen Excess Defined Kinetics Slope Changes

This method is used with Multi-point kinetic assays only. For samples being tested for Antigen Excess, the reaction rate (change in optical absorbance per change in unit time) measured over the first 3 readings (rate C) is compared to the reaction rate measured over the last 3 readings (rate D) and a rate difference is calculated. When this rate difference exceeds a predetermined threshold, an antigen excess condition flag is posted.

Method 3: Antigen Excess Defined Kinetics Slope Changes (page 4-6)

Method 1: Early Absorbance Read

The Antigen Excess flag is set at an absorbance level greater than the high calibrator absorbance when measured at the first read. The following graph illustrates this method of antigen excess detection.



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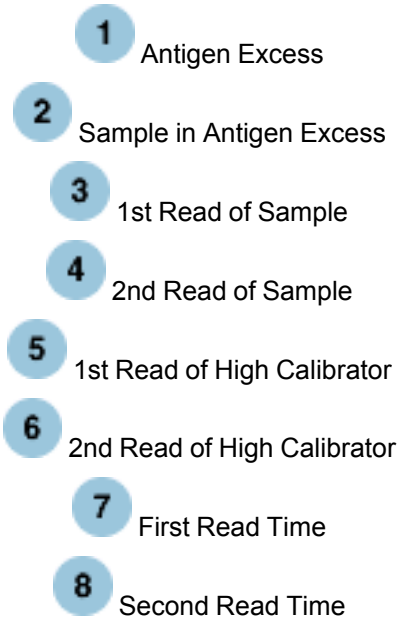

The Antigen Excess flag using the early absorbance read is empirically determined and is set in the following manner:

1. Run the high calibrator as a sample.
2. Touch the Kinetics Plot button on the Results Review screen.

   The system displays the Kinetic Plot screen.
3. Touch the Print Report button to view the absorbance value from the first read for the high calibrator.

RESULTS REVIEW - Kinetics Plot Data

==========

Current Sample ID: High Cal

Date/Time: 07/19/2008 04:20:00

User Defined Assay: 2PT

Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	10.00	0.80	0.041379
1	300.00	1.00	0.041379

==========

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4. Make up a series of samples that are elevated and likely to give Antigen Excess.
5. Run the samples in order of increasing concentration.
6. Use the Results Review screen to view sample information. The last sample that is outside the measuring (reportable) range should be viewed on the Kinetics Plot screen.
7. Touch the Kinetics Plot button on the Results Review screen. The system displays the Kinetic Plot screen.
8. Touch the Print Report button to view the last sample that is outside of the reportable range on the Kinetics Plot screen to obtain the absorbance of its first read.

RESULTS REVIEW - Kinetics Plot Data

==========

Current Sample ID: High Sample 3

Date/Time: 07/19/2008 04:20:00

User Defined Assay: 2PT

Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	10.00	1.30	0.062069
1	300.00	1.60	0.062069

==========

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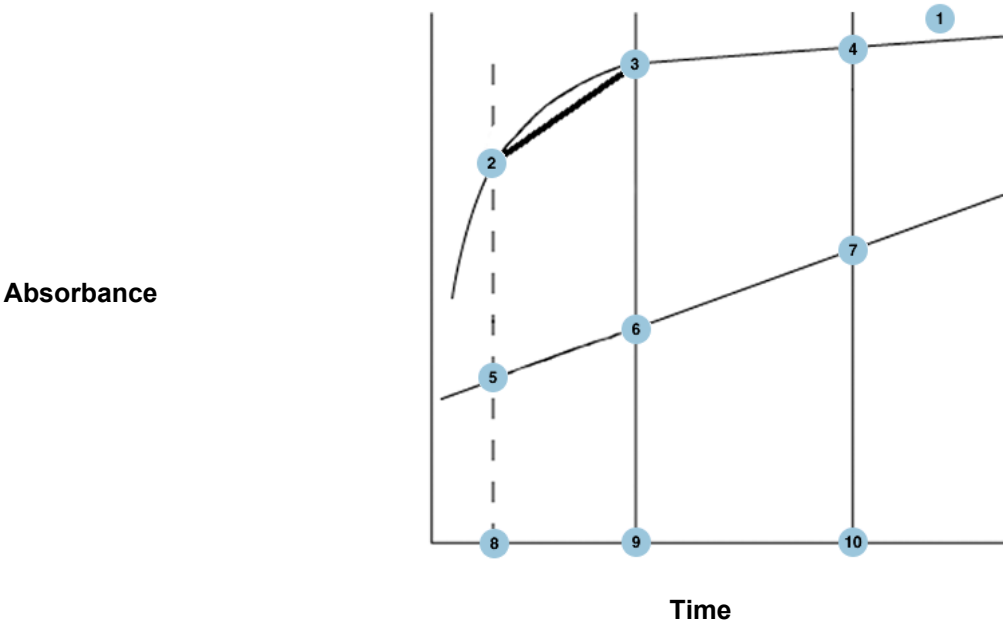
9 Calculate the Antigen Excess Factor by subtracting the absorbance of the high calibrator from the absorbance of the sample identified in step 6 (page 4-3).

For example, if the absorbance of the first read of the high calibrator is 0.80 and the absorbance of the first read of the selected sample (determined in step 6 above) is 1.30, the Antigen Excess Factor is 0.50.

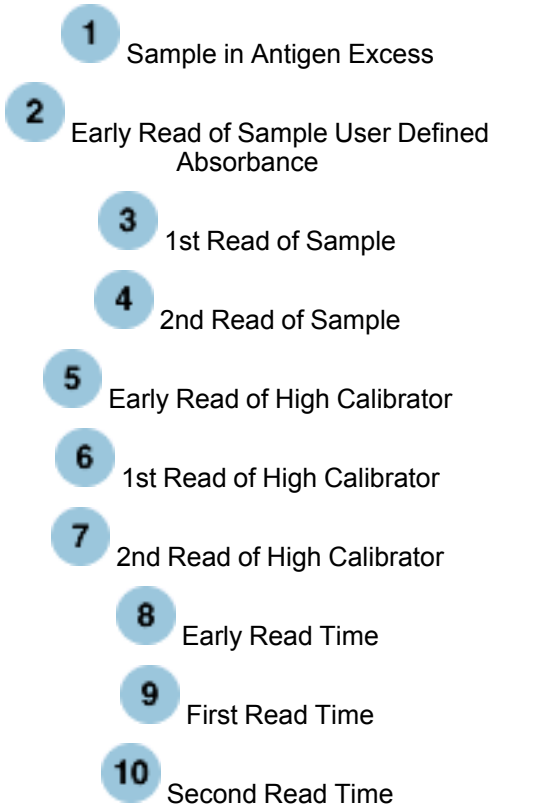
10 Type the **Antigen Excess Factor** on the Edit 2 Point Rate Additional Parameters screen.

Method 2: Early Rate Read

The early rate read method of determining Antigen Excess is preferred for samples with high turbidity because fewer false Antigen Excess flags are returned than in Method 1 (page 4-2). The following graph illustrates this method.



(Continued)



Set the Early Rate Read method using the following procedure:

1. Make up a series of samples that are elevated and likely to give Antigen Excess.
2. Run the samples in order of increasing concentration.
3. Use the Results Review screen to view sample information. The last sample that is outside the measuring (reportable) range should be viewed on the Kinetics Plot screen.
4. Touch the Kinetics Plot button on the Results Review screen.

   The system displays the Kinetic Plot screen.
5. Touch the Print Report button to view the absorbance and time of the early and first reads for the sample identified in step 3 (page 4-5).

RESULTS REVIEW - Kinetics Plot Data

==========

Current Sample ID: High Sample 4

Date/Time: 07/19/2008 04:20:00

User Defined Assay: 2PTAE

Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	1.00	0.80	0.062069
1	10.00	1.30	0.062069
1	300.00	1.60	0.062069

==========

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6 Type the slope in the **Antigen Excess Factor** field in the Edit 2 Point with Antigen Excess Rate Check Additional Parameters screen.

A slope is determined using the early read and the first read:

Δ absorbance ÷ Δ time in minutes = slope

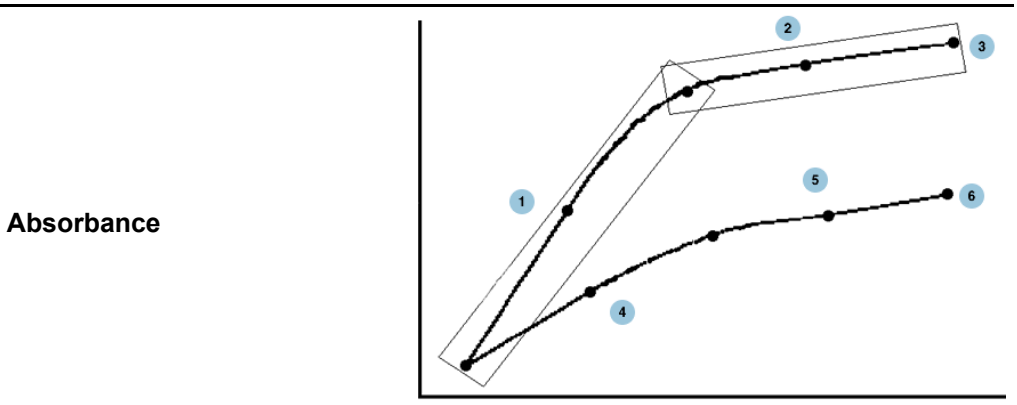
For example, if the read for the early read taken at 1 second had an absorbance of 0.80 and the first read taken at 10 seconds had an absorbance of 1.30, the Antigen Excess Factor is 3.333. Slope = 1.30 – .08 ÷ 0.15 minutes = 3.333

7 The **Early Rate Read Index** field allows the operator to select which read is excluded from the final response in the Antigen Excess rate check.

- Typing the number 1 instructs the software to not use the early read information when determining analyte concentration (the first and second read will be used).
- Similarly, typing a number 2 eliminates the first read in calculations for analyte predictions (early and second reads are used in the two-point rate equation).

Method 3: Antigen Excess Defined Kinetics Slope Changes

Multi-point rate assays must use this method to detect Antigen Excess. This method can only be used for assays with 4 or more read points. The following graph illustrates this method. If the difference for the unknown sample (Slope C minus Slope D) exceeds the Antigen Excess limit, a condition code is posted. The calibrator level 3 is provided for reference only, and does not enter into the calculation for excess antigen.



1 Slope C

2 Slope D

3 Sample in Antigen Excess

4 Slope A

5 Slope B

6 High Calibrator

The Antigen Excess flag using kinetics slope changes is empirically determined and is set in the following manner:

1 Make up a series of samples that are elevated and likely to give Antigen Excess.

2 Run the samples in order of increasing concentration.

3 Use the Results Review screen to view sample information. The last sample that is outside the measuring (reportable) range should be viewed on the Kinetics Plot screen.

4 Touch the Kinetics Plot button on the Results Review screen.

The system displays the Kinetic Plot screen.

5 Touch the Print Report button to view the absorbance and time of the early and first reads for the sample identified in step 3 (page 4-7) using the Kinetics Plot screen in Results Review.

- Calculate (using least squares regression) the slope for the first three points
- Calculate the slope for the last three points

Note: This method applies to assays with 4 to 12 reads. Assays with 4 or 5 reads will share points when making slope calculations. A three point kinetic will effectively disable the check.

RESULTS REVIEW - Kinetics Plot Data

==========

Current Sample ID: High Sample 4

Date/Time: 07/19/2008 04:20:00

User Defined Assay: NPT

Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	100.00	1.00	0.172800
1	150.00	1.35	0.172800
1	200.00	1.55	0.172800
1	250.00	1.59	0.172800
1	300.00	1.60	0.172800

==========

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In the example above, the slope of the first three points is 0.33 and the slope of the last three points is 0.03.

6 Calculate the absolute value of the difference of the slope of the first three read points and the slope of the last three read points to detect a drop of the kinetic activity indicating Antigen Excess conditions.

The **Antigen Excess Limit** from the example would be the absolute difference of 0.33 and 0.03, or 0.30.

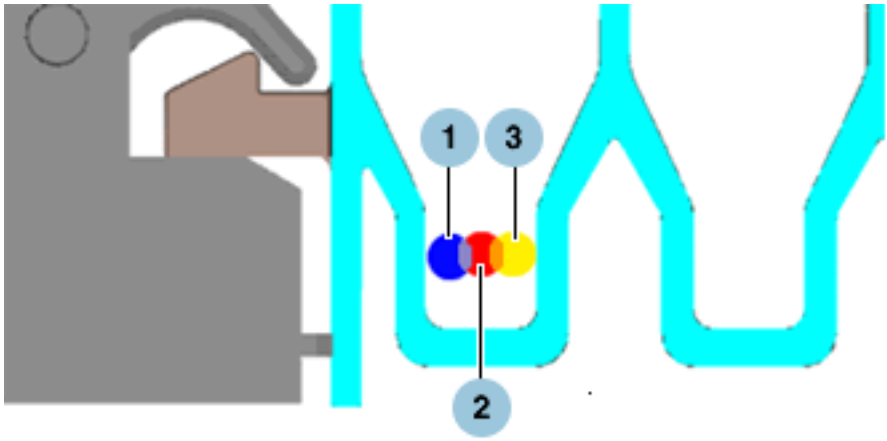
7 Type the **Antigen Excess Limit** on the Edit Multi-Point Additional Parameters screen. See Configure Result Parameters (page 2-7) for more information.

The additional fields on this screen are not related to Antigen Excess. Please refer to the help text for this screen for more information about these fields.

Chapter 5 Triple Read Algorithm Overview

Triple Read Algorithm Overview

Triple reads are performed for each cuvette to detect imperfections (air bubbles, atypical aggregates in liquids, etc.) that can affect concentration prediction. For each cuvette, the system performs optical reads at three different locations as illustrated below. A response is calculated at each location. The maximum difference among the three responses should be smaller than the triple read bias limit.



1 Cuvete Cell Read #1

2 Cuvete Cell Read #2

3 Cuvete Cell Read #3

In a User Defined Assay, you can define bias limits in concentration on an assay by assay basis to detect imperfections in the optical path balanced against inappropriately rejecting an acceptable result. See Configure Triple Read Parameters (page 2-18) for more information. The bias limit can be based on either clinical need or analytical capability.

Touch a link below to read more about bias limits in concentration:

- Triple Read Parameter Defaults (page 5-1)
- Triple Read Parameters Adjustment (page 5-2)

Triple Read Parameter Defaults

The default Critical Concentration is the midpoint of the Measuring (Reportable) range. See Configure Result Parameters (page 2-7) for more information.
From the Measuring (Reportable) Minimum to the Critical Concentration, the default triple read limit is 8% of the Critical Concentration (constant bias domain).
From Critical Concentration to the Measuring (Reportable) Maximum, the default triple read limit is 8% of the concentration (constant % bias, variable bias domain).

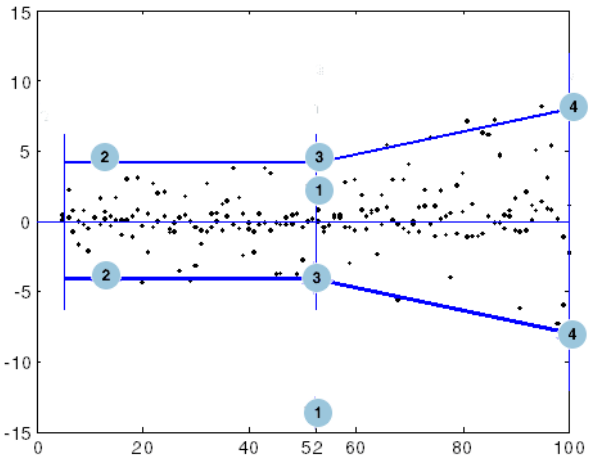
Default Triple Read Limit

The Edit Triple Read Parameters dialog box is represented by the following table. The values represent the default triple read limit.

	Measuring (Reportable) Concentration	Triple Read Limit
Measuring (Reportable) Min:	4	2 4.16
Critical Concentration:	1 52	3 8.0%
Measuring (Reportable) Max:	100	4 8.0%

The following figure illustrates the default triple read limit.

Default Triple Read Limit



1	Critical Value = (Max − Min) ÷ 2 + Min = (100 − 4) ÷ 2 + 4 = 52
2	Bias at Min Value = [Critical] × 0.08 = 4.16
3	Bias at Critical Value = [Critical] × (8 ÷ 100) = 4.16
4	Bias at Max Value = [Max] × (8 ÷ 100) = 8.00

Triple Read Parameters Adjustment

Change the default triple read limits and the critical concentration when necessary. Tightening the triple read limits may cause more results to be suppressed. If you experience a large number of condition codes (U91-274) during assay optimization, the limits can be relaxed. This returns more results for review. Refer to the following table to define the limits for triple read.

The following table represents the Edit Triple Read Parameters dialog box.

	Measuring (Reportable) Concentration	Triple Read Limit
Measuring (Reportable) Minimum	Cmin*	**Real Number (>0.0)**
Critical Concentration (CO)	**CO**	**% of CO**
Measuring (Reportable) Maximum	Cmax*	**% of Cmax**

* The measuring (reportable) minimum and maximum can only be adjusted on the Options & Configuration – Edit Result Parameters screen. See Configure Result Parameters (page 2-7) for more information.
The triple read limits are the allowable bias defined at Measuring (Reportable) Minimum, Critical Concentration, and Measuring (Reportable) Maximum.
Bias in concentration = real concentration − predicted concentration.

- The critical concentration (CO) can be adjusted by typing a concentration value within the measuring (reportable) range. The critical concentration is the point at which medical decisions are made between normal and abnormal test results.
- The triple read limit corresponding to measuring (reportable) minimum must be a bias in concentration value (Real Number).
- The triple read limit corresponding to critical concentration is defined as a percentage of the critical concentration (% of CO).
- The triple read limit corresponding to measuring (reportable) maximum is defined as a percentage of the measuring (reportable) maximum (% of Cmax).

Relaxed Adjusted Triple Read Limits

The following table represents the Edit Triple Read Parameters dialog box. The values represent a relaxed triple read limit across the measuring (reportable) range.

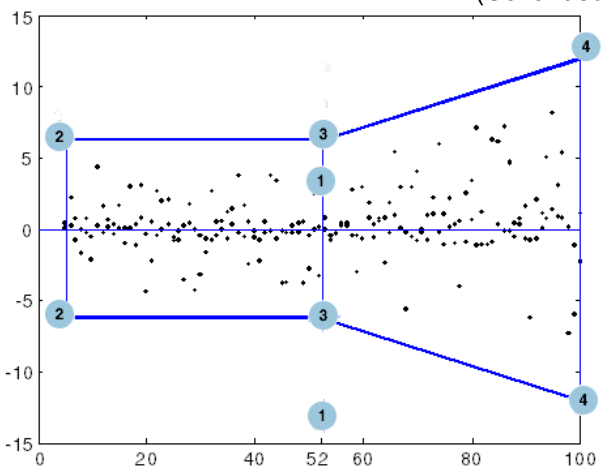
	Measuring (Reportable) Concentration	Triple Read Limit
Measuring (Reportable) Min:	4	2 6.25
Critical Concentration:	1 52	3 12 %
Measuring (Reportable) Max:	100	4 12 %

The following figure illustrates a relaxed triple read limit across the measuring (reportable) range.

Increase Triple Read Limit

(Continued)

Bias



Concentration

1	Critical value = Default
2	Bias at Min value = [Critical] × (12 ÷ 100) = 6.25
3	Bias at Critical value = [Critical] × (12 ÷ 100) = 6.25
4	Bias at Max value = [Max] × (12 ÷ 100) = 12.0

Adjusted Triple Read Limits with a Different Critical Concentration

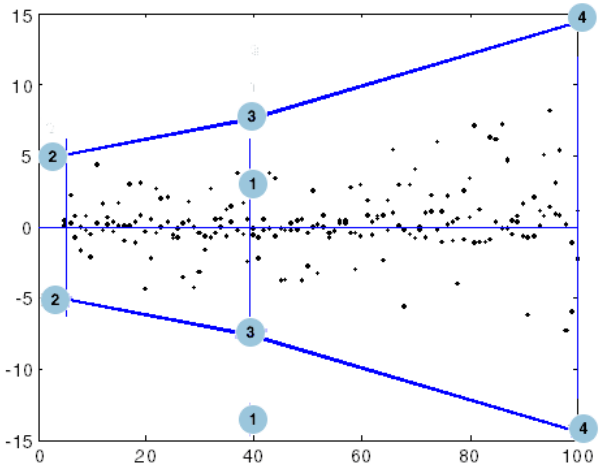
The following table represents the Edit Triple Read Parameters dialog box. The values represent adjusted triple read limits with a different critical concentration.

	Measuring (Reportable) Concentration	Triple Read Limit
Measuring (Reportable) Min:	4	2 5
Critical Concentration:	1 40	3 18 %
Measuring (Reportable) Max:	100	4 14 %

The following figure illustrate adjusted triple read limits with a different critical concentration.

Adjusted Triple Read Limit

(Continued)



Bias

Concentration

1	Critical value defined at 40
2	Bias at Min value defined as 5
3	Bias at Critical value = [Critical] × (18 ÷ 100) = 7.2
4	Bias at Max value = [Max] × (14 ÷ 100) = 14.0

Adjusted Triple Read Limits with a Different Critical Concentration and Higher Bias Limit

The following table represents the Edit Triple Read Parameters dialog box. The values represent an adjusted triple read limit with a different critical concentration and a higher bias limit at measuring (reportable) minimum than the bias limit at the critical concentration.

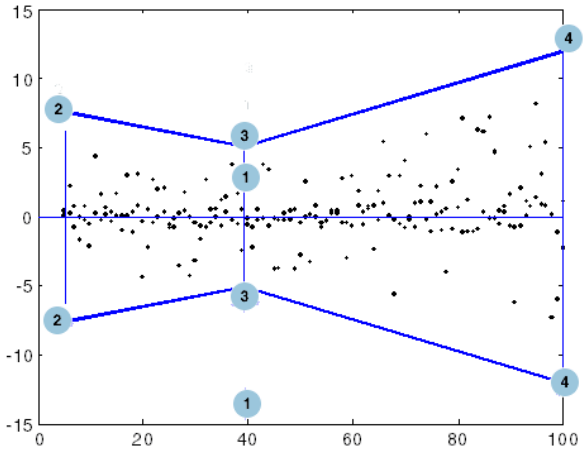
	Measuring (Reportable) Concentration	Triple Read Limit
Measuring (Reportable) Min:	4	2 7.5
Critical Concentration:	1 40	3 12 %
Measuring (Reportable) Max:	100	4 12 %

The following figure illustrates an adjusted triple read limit with a different critical concentration and a higher bias limit at measuring (reportable) minimum than the bias limit at the critical concentration.

Adjusted Triple Read Limit

(Continued)

Bias



Concentration

1	Critical value defined at 40
2	Bias at Min value defined as 7.5
3	Bias at Critical value = [Critical] × (12 ÷ 100) = 4.8
4	Bias at Max value = [Max] × (12 ÷ 100) = 12

Chapter 6 Molar Extinction Coefficient

Special requirements: **UDA Molar Extinction Coefficient Guidelines**

The Cal Model Type of Linear must be selected when first setting up the UDA.

UDA features that require input are:

- Reagent Lot information
- Result Parameters
- Protocol Parameters

Note: Cal Params do not require input.

1 After appropriate parameters have been entered, touch **Reagents** on the Status Console and load the UDA reagent pack.

Note: If no reagent is loaded for the assay, you cannot access the Options & Configuration – User Calibrate screen

2 On the Options and Configuration screen, touch **Review/Edit Calibrations**.

3 On the Options and Configuration – Review/Edit Calibrations screen, select the UDA assay and then touch the **User Calibrate** process button.

This button displays the Options & Configuration – User Calibrate screen.

4 Select the reagent pack lot number from the **Reagent Lot** pulldown.

5 Input the **Intercept** and **Slope**.

Intercept = Response when distilled water is run as a sample.

Slope = (Sv × ME) ÷ (Tv × 1000 mL/L × DIL).

- Sv = Sample volume (mL)
- ME = Molar Extinction coefficient in cm2/µmol

  (example: NADH = 6.25 at 340 nm)
- Tv = Total reaction volume (mL) (sample + reagent)
- DIL = Dilution factor of sample prior to being added to cuvette.

Note: Results from above calculations are either in µmol/min or µmol/L.

6 Touch the Save button to save your changes.

Note: Results reported will display a "UC" code notifying the user that the result is based on a User Calibration.

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Chapter 7 Quick Reference Table

UDA Guidelines

The following table provides the requirements for performing User Defined Assays.

Item	Requirement
Available fluid types	Serum
Assay Model Type	End Point Templates: Two-point Rate Templates: Two-point with Antigen Excess Rate Check Templates: Multi-point Rate Templates: • *EPT1 R1-S-R2 • EPT1 R1-S • EPT1 R1-R2-S • EPT2 R1-S • EPT2 R1-S-R2 • EPT2 R1-R2-S • *2PT R1-S-R2 • 2PT1 R1-S • 2PT1 R1-R2-S • *2PTAE R1-S-R2 • 2PTAE R1-S • 2PTAE R1-R2-S • NPT1 R1-S • NPT1 R1-S-R2 • NPT1 R1-R2-S
Calibration models and levels	• Linear Regression (2 levels minimum) • Cubic Spline (4 levels minimum) • Logit/Log4 (5 levels minimum) • Logit/Log5 (6 levels minimum)
Sample volume range	2–60 µL in 0.1 µL increments
Cuvette volume range	150–250 µL
Reagent volume Ranges	R1: 30–200 µL R2: 9–110 µL All reagent volumes are defined in 0.1 µL increments.

Reagent pack and diluent pack volumes	**IMPORTANT:** Use only VITROS system reagent packs.		
	Bottle Volume	**Recommend Maximum Fill Volume**	**Dead volume**
	A	15 mL	1.7 mL
	B	15 mL	0.4 mL
	Caution: Overfilling reagent pack bottles may create bubbles, foam, and form a thin film, preventing the system from operating correctly. Never fill over bottom of neck.		
Dilution factors	Supported dilution factors are 1 (for non-diluted samples), 1.3–101.		
Minimum total mix volume	96 µL		
Temperatures	Reagent storage temperature in SUPPLY 3 is 8°C ± 2°C Cuvette incubator reaction temperature is 37°C		
Wavelengths	The following wavelengths are provided for assay evaluation:		
	340 nm	510 nm	620 nm
	380 nm	540 nm	660 nm
	405 nm	575 nm	700 nm
	450 nm	600 nm	800 nm

Absorbance range	The acceptable absorbance range of the PHOTOMETER is -0.2 to 2.7 AU (absorbance units)
Calibration flags	Flags can be set for: • Decreasing Monotonicity • Increasing Monotonicity • Increasing Rate
Total assay run time	1800 seconds (30 minutes) on the system
Earliest read time after fluid addition	9.5 seconds
UDA naming conventions	Supported UDA name lengths: • Long name: 20 alphanumeric characters • Short name: 5 alphanumeric characters

Chapter 8 User Defined Assay Worksheet

Use the UDA Worksheet to organize and record data about your user-defined assay.

Note: Fields that do not contain an asterisk (*) are not required.

IMPORTANT: Fields that contain an asterisk (*) require an entry to initiate UDA processing.

*Full assay name:		
*Short assay name:	*Fluid type:	
*Assay model type:	*Template:	
*Cal model type:	*Calibrator bottles:	*Replicates per Cal:
	Result Parameters	
*Units:	Significant Digits:	User Adjusted Slope:
	Precision Digits:	User Adjusted Intercept:
CuveTip Expiration Time:	Temperature Sensitive: Yes ___ No ___	
Reference Range: ___ to ___	Supplementary Range: ___ to ___	Measuring (Reportable) Range: ___ to ___
Initial Absorbance Limits:	Second/Blank Absorbance Limits:	Early Rate Read Index:
Antigen Excess Factor:	Antigen Excess Limit:	Nonlinearity Limit:
Increasing Rate Flag: Yes ___ No ___	Max. Relative SD of Regression Line:	
Min. Read Points Allowed:	Max. SD of Regression Line:	
	Dilution Parameters	
Diluent:	Standard Dilution Factor:	
Reflex Dilution: On ___ Off ___	Reflex Dilution Factor:	Reduction factor:

Calibration Parameters Note: Not required if user calibrating assay.

*Kit lot	*Bottle number	*Dilution Factor	*Calibrator Replicate Response Range	*Calibrator Value
	1			
	2			

(Continued)

3	
4	
5	
6	

More Cal Parameters

Monotonicity:	Max. Response High:	Max. Response Low:
Cal. Fit Goodness Limit:	Min. Response High:	Min. Response Low:
Calibration Interval:		

Protocol Parameters

*Step	*Reagent		*Sample		*Incubation time	*Read Wavelength
	*Pack Name	*Volume	*Name	*Volume		
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
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Reagent Lot Information		
*On Board Stability:	*Reagent Lot Number:	*Shelf Expiration Date:
Triple Read Parameters		
Critical Concentration:	Reportable Min. Triple Read Limit:	
Reportable Concentration :	Critical Concentration Triple Read Limit:	
	Reportable Max. Triple Read Limit:	

Worksheet Key

Use the UDA Worksheet Key to understand information on the UDA Worksheet.

User Defined Assays Main Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Assay Button		1-20 (Assay IDs 980-999)
Full assay name		Up to 20 characters
Short Assay Name		Up to 5 characters
Fluid Type	Serum	Serum is currently the only available option.

(Continued)

Assay Model Type	None	• None • 2 Point Rate • 2 Point with Antigen Excess Rate Check • End Point • Multi Point
Template	• 2PT R1-R2-S • R1 = Reagent 1 • R2 = Reagent 2 • S = Sample • Listed in order of addition	• *2PT R1-S-R2 • *EPT1 R1-S-R2 • *2PTAE R1-S-R2 • 2PT R1-R2-S • 2PT R1-S • 2PTAE R1-R2-S • 2PTAE R1-S • EPT1 R1-R2-S • EPT1 R1-S • EPT2 R1-R2-S • EPT2 R1-S • EPT2 R1-S-R2 • NPT R1-R2-S • NPT R1-S • NPT R1-S-R2
Calibration Model Type	Logit/Log4	• Logit/Log4 • Linear • Logit/Log5 • Cubic Spline
Calibrator Bottles		1 to 6
Reagent Reps per Cal		1 to 40

Edit Result Parameters Screen

Parameter	Default	Ranges/Limits/Available Options
Units		
Significant Digits	6	1 to 6
Precision Digits	3	0 to 3
User Adjusted Slope	1.0	-999999000 to 999999000 0 is not allowed
User Adjusted Intercept	0.0	-900000000 to 900000000

(Continued)

CuveTip Expiration Time	35	5 to 35 minutes in 5 minute increments
Temperature Sensitive	Disabled	Disabled or Enabled
Reference Range	0 to 900000000	0 to 900000000
Supplemental Range	0 to 900000000	0 to 900000000
Measuring (Reportable) Range	0 to 10000	-900000000 to 900000000
Qualitative Ranges (Qualitative Reporting Types only)	2	2–5
Report Qualitative Result Outside of Range (Qualitative only)	Disabled	Disabled or Enabled

Edit Result Additional Parameters Screen

Parameter	Default	Ranges/Limits/Available Options
Initial Absorbance Limits	-0.200 to 2.700	-0.200 to 2.700 2 Point Rate, 2 Point Rate with Antigen Excess Rate Check, End Point, Multi Point
Second Absorbance Limits	-0.200 to 2.700	-0.200 to 2.700 2 Point Rate, 2 Point Rate with Antigen Excess Rate Check
Blank Absorbance Limits	-0.200 to 2.700	-0.200 to 2.700 End Point
Antigen Excess Factor	9.0000	0.0000 to 10.0000 2 Point Rate, 2 Point with Antigen Excess Rate Check
Early Rate Read Index	1	1 to 3 2 Point with Antigen Excess Rate Check
Antigen Excess Limit	9.0000	0.0000 to 10.0000 Multi Point
Nonlinearity Limit	0.1000	0.0000 to 1000.0000 Multi Point
Increasing Rate Flag	Enabled	Enabled or Disabled Multi Point
Max. Relative SD of Regression	100.000	0.00 to 100.0000 Multi Point

(Continued)

Minimum Read Points Allowed	3	2 to 12 Multi Point
Max. SD of Regression Line	10.000	0 to 10 Multi Point

Edit Dilution Parameters Screen

Parameter	Default	Ranges/Limits/Available Options
Diluent	None	• None • Saline • BSA • Water • Specialty • Urine Electrolyte Diluent (UED) • ApoDiluent • DATDil2 • DATDil • Lysis Buff • User Defined Diluents
Standard Dilution Factor	1.0 (no dilution)	1.0, 1.3 to 101.0 in 0.1 increments
Reflex Dilution	Off	Off or On
Dilution Factor	1.0 (no dilution)	1.0 to 101.0 in 0.1 increments
Reduction Factor	1.0	0.1 to 1.0 in 0.1 increments

Edit Calibration Parameters Screen

Parameter	Default	Ranges/Limits/Available Options
Dilution Factor	1.0 (no dilution)	1, 1.3 to 101
Calibrator Replicate Response Range	0.20000	0 to 0.2
Kit Lot		1 to 99
Calibrator Value		-900000000 to 900000000

Edit Calibration Additional Parameters Screen

Parameter	Default	Ranges/Limits/Available Options
Monotinicity	Increase	Increase or Decrease

(Continued)

Max. Response High	3.00	-1000 to 1000
Max. Response Low	-3.00	-1000 to 1000
Min. Response High	3.00	-1000 to 1000
Min. Response Low	-3.00	-1000 to 1000
Cal Fit Goodness Limit	0.99	0.000 to 1.000 For Cal Model Types: Linear, Logit/Log4, Logit/Log5
Calibration Interval	999 days	1 to 999

Edit Protocol Parameters Screen

Parameter	Default	Ranges/Limits/Available Options
Protocol - Reagent (R1) Volume (µL)	150.0	30.0 to 200.0
Protocol - Reagent (R1) Pack Name/Bottle	Template dependent	UD01 (A or B) to UD20 (A or B)
Protocol - Reagent (R2) Volume (µL)	10.0	9.0 to 110.0
Protocol - Reagent (R2) Pack Name/Bottle	Template dependent	UD01 (A or B) to UD20 (A or B)
Protocol - Sample Volume (µL)	5.0	2.0 to 60.0
Protocol - Incubation Time (seconds)	Template dependent	Template dependent
Protocol - Read Wavelengentry (nm)	340 for End Point and Rate Reads. 540 for Blank Reads.	None 340.....510.....620 380.....540.....660 405.....575.....700 450.....600.....800

Reagent Lot Information Screen

Parameter	Default	Ranges/Limits/Available Options
On Board Stability (Days)		1 to 99
Reagent Lot Number		Any Printable Character (12 max)
Shelf Expiration Date		

Edit Triple Read Parameters Screen

Parameter	Default	Ranges/Limits/Available Options

(Continued)

Critical Concentration Reportable Concentration	Midpoint between the Measuring (Reportable) Range	-900000000 to 900000000
Reportable Min. Triple Read Limit	Critical Concentration × 8%	>0 to 900000000
Critical Concentration Triple Read Limit	8%	0.1 to 1000 percent in 0.1 increments
Reportable Max. Triple Read Limit	8%	0.1 to 1000 percent in 0.1 increments

Ortho Clinical Diagnostics

CE

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