

Safety Data Sheets for Donor Screening Products

Dear Valued Customer:

Ortho Clinical Diagnostics (OCD) provides Safety Data Sheets (SDS) for any OCD products that contain hazardous materials at or above regulated thresholds.

Under normal conditions of use, the products that contain hazardous substances would not expose the user to a chemical hazard. However, since some products may contain biological materials, standard precautions should be used when handling all products.

The list of Ortho Clinical Diagnostics' products or products distributed by OCD indicates the products that have an SDS and the products that are exempt and do not have an SDS.

- Those products with Yes in the first column of the list have an SDS. The SDS can be found at www.orthoclinical.com or on the listed manufacturer's website. Click the MSDS Library link in the lower right-hand corner of the page, select your country, and then follow the prompts in the screen to obtain the documents that you need. Print the SDS for your records.
- Those products with No in the first column of the list do not require an SDS. Print this exemption letter and file it to prove that an SDS is not required.

For more information on these products, please refer to the package insert or instructions for use (IFU). We recommend that you file this letter and the list of products with your SDS records for documentation purposes.

Thank you for your continued support of Ortho Clinical Diagnostics products.

Donor Screening Products – Safety Data Sheets (SDS) Information

Not all products and systems are available in all regions.

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Revision History

Date	Description of Change
2015-07-23	<ol style="list-style-type: none"> 1. Removed ORTHO® Summit Sample Handling System section 2. Removed AUTOWASH 96 section 3. Assay Barcode Labels (BCL) <ul style="list-style-type: none"> • Removed 936473, Demo Assay (ZZ) Plate Barcode Labels.
2014-12-15	<ol style="list-style-type: none"> 1. Reagents - ORTHO® HBc ELISA Test System <ul style="list-style-type: none"> • Removed 6902015, HBc ELISA, 5 plate. 2. Reagents – ORTHO® Generic <ul style="list-style-type: none"> • Updated product description 6904473, 2N Sulfuric Acid (Stop Solution) for Avioq® HTLV-I/II. 3. Reagents - Avioq® HTLV-I/II <ul style="list-style-type: none"> • Updated Catalog Codes from 200192, 200576, 209600, 259879 to 500192, 500576, 509600, 559879; added 559880. 4. ORTHO VERSEIA® Integrated Processor (VIP) <ul style="list-style-type: none"> • Added section. 5. ORTHO® Summit Processor (OSP) <ul style="list-style-type: none"> • Changed SDS requirement from “No” to “Yes” for 6902057, Microcide SQ &148473, Wash/Dispense User Verification Kit.

Donor Screening Products – SDS Information

Revision History

Date	Description of Change
	6. Added notation for discontinued products, where applicable.
2013-05-15	Initial release of document

Reagents - ORTHO® T. cruzi ELISA Test System

Reagents		
ORTHO® T. cruzi ELISA Test System		
SDS?	Catalog Code	Description
Yes	6901968	ORTHO® T. cruzi ELISA, 5 plate
Yes	6901969	ORTHO® T. cruzi ELISA, 25 plate

Reagents - ORTHO® HCV Version 3.0 ELISA Test System

Reagents		
ORTHO® HCV Version 3.0 ELISA Test System		
SDS?	Catalog Code	Description
Yes	930740	HCV 3.0 ELISA, 5 plate
Yes	930750	HCV 3.0 ELISA, 25 plate
Yes	6902511	HCV Enhanced SAVe, 5 plate
Yes	930800	HCV Enhanced SAVe, 5 plate
Yes	930820	HCV Enhanced SAVe, 2 plate

Reagents - ORTHO® HBc ELISA Test System

Reagents		
ORTHO® HBc ELISA Test System		
SDS?	Catalog Code	Description
Yes	933245	HBc ELISA, 5 plate
Yes	933275	HBc ELISA, 25 plate

Reagents - ORTHO® Generic

Reagents		
ORTHO® Generic		
SDS?	Catalog Code	Description
Yes	933730	Wash Buffer, Ortho, 20X Concentrate
Yes	933040	4N Sulfuric Acid, Stop Solution
Yes	6904473	2N Sulfuric Acid (Stop Solution) for Avioq® HTLV-I/II

Donor Screening Products – SDS Information

Reagents - GS HIV-1/HIV-2 PLUS O EIA

Note: OCD is the Sales Agent for the below listed Bio-Rad Genetic Systems products and does not distribute them.

Reagents		
GS HIV-1/HIV-2 PLUS O EIA		
SDS?	Catalog Code	Description
Yes http://www.bio-rad.com/	32588	GS HIV-1/HIV-2 PLUS O, 5 plate
Yes http://www.bio-rad.com/	25256	GS HIV-1/HIV-2 PLUS O, 50 plate
The following product codes are for individual reagents for GS HIV-1/HIV-2 PLUS O EIA		
Yes http://www.bio-rad.com/	26181	TMB/SUBSTRATE BUFFER
Yes http://www.bio-rad.com/	26182	TMB/CHROMOGEN
Yes http://www.bio-rad.com/	25122	CONJUGATE CONCENTRATE, GS HIV-1/HIV-2 PLUS O
Yes http://www.bio-rad.com/	25121	CONJUGATE DILUENT, GS HIV-1/HIV-2 PLUS O
Yes http://www.bio-rad.com/	25123	SPECIMEN DILUENT, GS HIV-1/HIV-2 PLUS O
Yes http://www.bio-rad.com/	25118	HIV 1 POSITIVE CONTROL, GS HIV-1/HIV-2PLUS O
Yes http://www.bio-rad.com/	25119	HIV 2 POSITIVE CONTROL, GS HIV-1/HIV-2 PLUS O
Yes http://www.bio-rad.com/	25120	HIV O POSITIVE CONTROL, GS HIV-1/HIV-2 PLUS O
Yes http://www.bio-rad.com/	25117	NEGATIVE CONTROL, GS HIV-1/HIV-2 PLUS O
Yes http://www.bio-rad.com/	25260	4N Sulfuric Acid (Stop Solution), Bulk Pack
Yes http://www.bio-rad.com/	25261	Wash Solution 30X, Bulk Pack

Donor Screening Products – SDS Information

Reagents - GS HBsAg EIA 3.0

Note: OCD is the Sales Agent for the below listed Bio-Rad Genetic Systems products and does not distribute them.

Reagents		
GS HBsAg EIA 3.0		
SDS?	Catalog Code	Description
Yes http://www.bio-rad.com/	32591	GS HBsAg 3.0 EIA, 5 plate
Yes http://www.bio-rad.com/	25258	GS HBsAg 3.0 EIA, 50 plate
Yes http://www.bio-rad.com/	32594	GS HBsAg Confirmatory, 25 tests
The following product codes are for individual reagents for GS HBsAg EIA 3.0:		
Yes http://www.bio-rad.com/	26181	TMB, SUBSTRATE BUFFER)
Yes http://www.bio-rad.com/	26182	TMB, CHROMOGEN
Yes http://www.bio-rad.com/	25103	CONJUGATE CONCENTRATE, GS HBsAg EIA 3.0
Yes http://www.bio-rad.com/	25104	CONJUGATE DILUENT, GS HBsAg EIA 3.0
Yes http://www.bio-rad.com/	25108	NEGATIVE CONTROL, GS HBsAg EIA 3.0
Yes http://www.bio-rad.com/	25109	POSITIVE CONTROL, GS HBsAg EIA 3.0
Yes http://www.bio-rad.com/	25110	LOW POSITIVE CONTROL, GS HBsAg EIA 3.0
Yes http://www.bio-rad.com/	25260	4N Sulfuric Acid (Stop Solution), Bulk Pack, 5/pkg
Yes' http://www.bio-rad.com/	25261	Wash Solution 30X, Bulk Pack

Donor Screening Products – SDS Information

Reagents - Avioq[®] HTLV-I/II

Reagents		
Avioq [®] HTLV-I/II		
SDS?	Catalog Code	Description
Yes http://www.avioq.com	500192	Avioq [®] HTLV I/II Microelisa System, 192 tests
Yes http://www.avioq.com	500576	Avioq [®] HTLV I/II Microelisa System, 576 tests
Yes http://www.avioq.com	509600	Avioq [®] HTLV I/II Microelisa System, 9600 tests
Yes http://www.avioq.com	559879	Wash Buffer Concentrate for Avioq [®] HTLV I/II Microelisa System (100 ml bottles)
Yes http://www.avioq.com	559880	Wash Buffer Concentrate for Avioq [®] HTLV I/II Microelisa System, (4 x 100 ml bottles)

Assay Barcode Labels (BCL)

Assay Barcode Labels (BCL)		
SDS?	Catalog Code	Description
No	6902520	ORTHO [®] HCV Version 3.0 ELISA Test System, Code 128, 1000 plate labels
No	6902521	ORTHO [®] HCV Version 3.0 ELISA Test System, Code 128, 4500 plate labels
No	6904588	ORTHO [®] HCV Version 3.0 ELISA Test System, Code 128, 7500 plate labels
No	6902522	ORTHO [®] HCV Version 3.0 ELISA Test System, Code 128, 150 control tube labels
No	935138	ORTHO [®] HBc, Code 128, 1000 count
No	935139	ORTHO [®] HBc, Code 128, 4500 count
No	6901907	GS HIV-1/HIV-2 PLUS O, code 128, 1000 count
No	6901908	GS HIV-1/HIV-2 PLUS O, code 128, 4500 count
No	6904590	GS HIV-1/HIV-2 PLUS O, code 128, 7500 count
No	6901909	GS HIV-1/HIV-2 PLUS O, Control tube labels, 150
No	6902195	GS HBsAg 3.0 EIA, code 128, 1000 count
No	6902196	GS HBsAg 3.0 EIA, code 128, 4500 count
No	6904589	GS HBsAg 3.0 EIA, code 128, 7500 count
No	6902197	GS HBsAg 3.0 EIA, Control tube labels, 150 sets
No	6902615	Demo Assay (ZZ) Barcode Labels, Specimen Diluent and Control Vial for ORTHO VERSEIA [™] Pipetter, 130 sets
No	6902323	ORTHO [®] T. cruzi Plate Barcode Labels, 1000 count

Donor Screening Products – SDS Information

Assay Barcode Labels (BCL)		
SDS?	Catalog Code	Description
No	6902324	ORTHO [®] T. cruzi Plate Barcode Labels, 4500 count
No	6902325	ORTHO [®] T. cruzi Control Barcode Label Sets (150 sets)
No	6904449	GS HBsAg EIA 3.0 Control Vial BCL (264 sets) for ORTHO VERSEIA™ Pipetter
No	6904450	GS HIV-1/HIV-2 PLUS O Control Vial BCL (260 sets) for ORTHO VERSEIA™ Pipetter
No	6904451	GS HIV-1/HIV-2 PLUS O Specimen Diluent BCL (420/pkg) for ORTHO VERSEIA™ Pipetter
No	6904452	ORTHO [®] HCV 3.0 Control Vial BCL (255 sets) for ORTHO VERSEIA™ Pipetter
No	6904453	ORTHO [®] HCV 3.0 Specimen Diluent BCL (420/pkg) for ORTHO VERSEIA™ Pipetter
No	6904454	ORTHO [®] T. cruzi Control Vial BCL (255 sets) for ORTHO VERSEIA™ Pipetter
No	6904455	ORTHO [®] T. cruzi Specimen Diluent BCL (420/pkg) for ORTHO VERSEIA™ Pipetter
No	6904470	Avioq [®] HTLV-I/II 4500 Plate BCL (Code 128) for ORTHO [®] Summit System
No	6904471	Avioq [®] HTLV-I/II 1000 Plate BCL (Code 128) for ORTHO [®] Summit System
No	6904472	Avioq [®] HTLV-I/II 150 Control Tube BCL (Code 128) for ORTHO [®] Summit System
No	6904572	Avioq [®] HTLV-I/II Specimen Diluent BCL (Code 128) for ORTHO [®] Summit System
No	6904573	Avioq [®] HTLV-I/II control Vial BCL (Code 128) for ORTHO [®] Summit System
No	6904574	ORTHO [®] HBc, Code 128, Control Vial BCL
No	6904575	ORTHO [®] HBc, Code 128, Specimen Diluent BCL

Ancillary Assay Items

Ancillary Assay Items		
SDS?	Catalog Code	Description
No	6904477	Uncoated Plates for Avioq
No	50000311	Plate Frames (8 x 12), Dynatech, (HBc)
No	TAH9001	Clear Filler Strips, (HBc)
No	50000312	Divida Strip, White, (HCV)
No	50000328	Blank Costar Filler Strips (ORTHO [®] T.cruzi)
No	AH0001	Microwell Remover/Plate Leveler
No	TAH1006	Plate Covers, Black

Donor Screening Products – SDS Information

ORTHO[®] Assay Software (OAS)

ORTHO [®] Assay Software (OAS)		
SDS?	Catalog Code	Description
No	936416/936416F	OAS Server – 450 MHz, Refurbished (Discontinued)
No	6902379	Smart UPS 750 (Discontinued)
No	6842840	SuperMicro Super Server Base System Server for OAS (LINUX), includes the keyboard and mouse
No	6904466	New Server UPS 2200 (LINUX) (Discontinued)
No	6904311	OSS Monitor
No	937973	Intel Keyboard
No	6902378	Modem for OAS Server
No	6902257	Linksys Etherfast 10/100 16 port Hub, Model EFAH16W (LIST) (Discontinued)
No	6903102	Linksys Cisco Catalyst 3560G-48TS Switch (Discontinued)
No	6903023	OSS Printer
No	937978	Surge Arrest (for Printer, AutoReader, and Summit)
No	936415F	OAS 400 MHz Workstation
No	50000734	RJ45/BD25F Adaptor, OAS Workstation
No	6902300	Smart-UPS SC420 for OAS 400 MHz WS and Standalone Server/Workstation
No	6902114	HHP Barcode Scanner
No	6902304	HHP IMAGETEAM 5600 Barcode Scanner, specifically for OSP
No	50000727	3 Foot Patch Cable
No	TCL1015	10 Foot Patch Cable
No	TCL1066	25 Foot Patch Cable
No	TCL1145	50 Foot Patch Cable
No	TCL1146	100 Foot Patch Cable
No	6801358	Universal UPS for DS, replacing 6904466, 6902379, 934231, and 6902300
No	6904586	Cisco SGE2000 24-Port Gigabit Switch

ORTHO[®] Assay Protocol Disk (OAPD)

ORTHO [®] Assay Protocol Disk (OAPD)		
SDS?	Catalog Code	Description
No	938220	ORTHO [®] HCV 3.0, Version 2.0.0, Rev. 1 → Rev. 3 (8-h OPD stability)
No	938246	ORTHO [®] HBc, Version 2.0.0, Rev. 1
No	6901910	GS HIV-1/HIV-2 PLUS O, Version 2.0.0, Rev. 2

Donor Screening Products – SDS Information

ORTHO [®] Assay Protocol Disk (OAPD)		
SDS?	Catalog Code	Description
No	6902194	GS HBsAg 3.0 EIA, Version 2.0.0, Rev. 2
No	938261	Demo Assay, Version 2.0.0, Rev. 1
No	6902488	ORTHO [®] T. cruzi, Version 2.0.0, Rev. 5 → Rev. 7 (8-h OPD stability)
No	6904468	Avioq [®] HTLV-I/II, Version 3.0, Rev. 3
ORTHO [®] Assay Protocol Disks (OAPDs) for LINUX Server Only (DVD format):		
No	6904456	ORTHO [®] T. cruzi OAPD, DVD format
No	6904457	ORTHO [®] HCV 3.0 OAPD, DVD format
No	6904458	ORTHO [®] HBc OAPD, DVD format
No	6904459	Demo OAPD, DVD format
No	6904460	GS HIV-1/HIV-2 PLUS O OAPD, DVD format
No	6904461	GS HBsAg EIA 3.0 OAPD, DVD format
No	6904469	Avioq [®] HTLV-I/II, DVD format

ORTHO VERSEIA[®] Pipetter

ORTHO VERSEIA [®] Pipetter		
SDS?	Catalog Code	Description
No	5561701	ORTHO VERSEIA [™] Pipetter; includes: 5611001, 5519101, 5930001, 5975501, 182085, 173410, 185290, 6904463, 190070
No	5163102	Cabinet for the ORTHO VERSEIA [™] Pipetter
No	6842852 (6842852B)	ORTHO VERSEIA [™] Pipetter Workstation; includes Monitor, Keyboard, Mouse, and hand-held barcode scanner
No	6902616	Supplemental Software Disk
No	50000727	3 Foot Patch Cable
No	TCL1015	10 Foot Patch Cable
No	TCL1066	25 Foot Patch Cable
No	TCL1145	50 Foot Patch Cable
No	TCL1146	100 Foot Patch Cable
No	6902677	Cisco 851 Firewall Router
No	173410	Sample Carrier
No	6904463	Tube Filling Rack/Carrier Holder
No	190070	Carrier Transport Rack
No	5611001	Storage Tray
No	182085	Tip Carrier

Donor Screening Products – SDS Information

ORTHO VERSEIA® Pipetter		
SDS?	Catalog Code	Description
No	5975501	Plate and Tip Carrier
No	185290	Reagent Carrier
No	5519101	OCD Assay Control Carrier
No	5930001	Bio-Rad Assay Control Carrier
No	6427001	Small Control Carrier Adapter
No	235904	High Volume (1,000 µL) Diluent Tips
No	235902	Standard Volume (300 µL) Sample Tips
No	182703	Reagent Containers
No	281520	Trash Can, Biohazard Box
No	185319	Plastic Tip Chute
No	5547401	Bags, Biohazard
No	220382	Removal Kit for the ORTHO VERSEIA™ Pipetter
Yes	937924	ORTHO® Pipetter Volume Verification Kit
No	V173402	Sample Rack Finger Grip

ORTHO VERSEIA® Integrated Processor (VIP)

ORTHO VERSEIA® Integrated Processor (VIP)		
SDS?	Catalog Code	Description
No	6695601	VIP Hardware Conversion Kit for OSP
No	6695901	VIP Hardware Conversion Kit for Verseia
No	6571801	Rack, CAR 6T, 3STK, 1MTP
No	6571901	Rack, CAR 6T,5STK
No	182074	Nested Tip Carriers
No	235950	300 uL Stacked Tips
No	6904638	VIP Software
No	90737	DTx VIP Accessory Kit
No	6803901	ORTHO VERSEIA® & VIP Trash Can, Biohazard Box, 10/case
No	6711103	ORTHO VERSEIA® & VIP Bags, Biohazard, 10/case

Donor Screening Products – SDS Information

ORTHO® Summit Processor (OSP)

ORTHO® Summit Processor (OSP)		
SDS?	Catalog Code	Description
No	936480	ORTHO® Summit Processor (16/20)
No	148317(F)	OSP Expansion Module from 16/20 to 24/20
No	146022 146022F	OSP 24/20 Includes 936480 and 148317
No	934231	OSP UPS (Discontinued)
No	936396	OSP Workstation, 166 MHz
No	6904311	ORTHO® Summit System 17 inch Flat screen Monitor for OAS and OSP
No	937973	Keyboard
No	6902304	HHP Barcode Scanner, specifically for OSP
No	936474	Reagent Barcode Label Set
No	936475	Wash Fluid Container Stand
No	936476	Waste Container
No	936477	Wash Fluid Container
No	T279650	Wash Fluid Container Cap
No	936574	OSP Photometer Verification Plate
No	936575	Incubator Verification Plate
No	147692	OSP Disposable Syringes
No	148482	OSP Reagent Containers
Yes*	6902057	Microcide SQ * Go to Siemens website and search “Microcide” in the Description (manufacturer’s product code 06984605):: https://www.healthcare.siemens.com/doclib/jsp_doclib_public/doclib_homePage.jsp?doclibId=1&locale=en_US&tabId=3
Yes*	148473	Wash/Dispense User Verification Kit * Possibly not posted – Future posting to occur
No	T147179	Reagent Container Carousel
No	T230005	Check Plate for Cold Start
No	T147936	Manifold Cleaning Set
No	T281110	OSP Plugs, Manifold
No	T5613501	Wash Manifold Plug
No	T281153	Sterile Filter
No	T148333	Spillage Tray

Donor Screening Products – SDS Information

ORTHO [®] Summit Processor (OSP)		
SDS?	Catalog Code	Description
No	147660	OSP Entry Stack
No	T5844401	Barcode Labels, External Pump Station Washer 1
No	T5844402	Barcode Labels, External Pump Station Washer 2 for 24/20 configuration
No	T5815001	Barcode Labels (OCD-specific Wash Fluid Container Barcodes Washer 1)
No	T5815002	Barcode Labels (OCD-specific Wash Fluid Container Barcodes Washer 2)
No	T5815003	OSP GS WASH BARCODE LABELS W1 (GS 30X W1)
No	T5815004	OSP GS WASH BARCODE LABELS W2 (GS 30X W2)
No	T5815005	RINSE BARCODE LABELS W1 (Rinse Sol 1)
No	T5815006	RINSE BARCODE LABELS W2 (Rinse Sol 2)
No	T5815007	Barcode Labels (Maintenance Fluids Washer 1)
No	T5815008	Barcode Labels (Maintenance Fluids Washer 2)
No	T5815009	Barcode Labels (Generic Wash Fluid Container Barcodes)
No	T5815010	OSP Avioq HTLV WASH BARCODE LABELS W1 (Avioq 25X W1)
No	T5815011	OSP Avioq HTLV WASH BARCODE LABELS W2 (Avioq 25X W2)
No	5733801	OSP 24/20 base cabinet, currently only available for CSL
No	T235436	OSP 610nm Photometer 2 Optical Filter for <i>T. cruzi</i>
No	T235525	OSP 610nm Photometer 1 Optical Filter for <i>T. cruzi</i>

Autoreader IV

AUTOREADER IV (ARIV)		
SDS?	Catalog Code	Description
No	6902093	AutoReader IV
No	6902094	AutoReader IV QC Multi-pac
No	TS039315	Lamp, 8V, 50 Watt for AutoReader IV
No	B03631002	Optical Filter Carriage with 6-filter slide for AutoReader IV
No	TS039318	Power Fuse for AutoReader IV
No	TS039302	Air Filter for AutoReader IV
No	B01662501	Interface Cable for AutoReader IV