



## STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-GEN-002 JA1

**DOCUMENT TITLE:**

Certificates of Analysis and/or Certificates of Conformance JA1

**DOCUMENT NOTES:**

6D.820.01 (JA1)

### Document Information

**Revision:** 05

**Vault:** STCL-General-rel

**Status:** Release

**Document Type:** STCL

### Date Information

**Creation Date:** 08 Oct 2021

**Release Date:** 18 Mar 2022

**Effective Date:** 18 Mar 2022

**Expiration Date:**

### Control Information

**Author:** WATER002

**Owner:** WATER002

**Previous Number:** STCL-GEN-002 JA1 Rev 04    **Change Number:** STCL-CCR-522

**STCL-GEN-002 JA1****Certificates of Analysis and/or Certificates of Conformance**

The following is a list of products utilized in the Stem Cell Laboratory that require Certificates of Analysis (CoA) and/or Certificates of Conformance (CoC). The list includes instructions on how to obtain the certificates if they do not accompany the product. **NOTE:** The products and vendors are subject to change based on industry manufacturing; at the time of release, this document was current.

Product	Certificate of Analysis Obtained by:
<b>ACD, FORMULA A</b>	Request @ <a href="mailto:MPCS_COA_Requests@baxter.com">MPCS_COA_Requests@baxter.com</a>
<b>AEROSPRAY Nozzle Cleaning Solution</b>	Request online <a href="mailto:docontrol_ebs@elitechgroup.com">docontrol_ebs@elitechgroup.com</a>
<b>ANTICOAGULANT SODIUM CITRATE</b>	Online at <a href="http://certificates.freseniuskabiusa.com/Pages/CHome.aspx">http://certificates.freseniuskabiusa.com/Pages/CHome.aspx</a>
<b>BENZONASE</b>	Request online @ <a href="http://emdmillpore.com">http://emdmillpore.com</a>
<b>BIOARCHIVE CANISTERS</b>	Certificate of Conformance INCLUDED
<b>BIOARCHIVE OVERWRAP BAGS</b>	Certificate of Conformance INCLUDED
<b>BLOOD CULTURE BOTTLES (BacT)</b>	Certificate of Conformance <a href="http://www.biomeriux.com">http://www.biomeriux.com</a>
<b>BLUNT END NEEDLES</b>	Request online from Stem Cell Technologies <a href="http://www.stemcell.com/">http://www.stemcell.com/</a>
<b>BONE MARROW COLLECTION KIT</b>	Online at <a href="http://certificates.freseniuskabiusa.com/Pages/CHome.aspx">http://certificates.freseniuskabiusa.com/Pages/CHome.aspx</a>
<b>CLEANWARE AQUA CLEAR WATER BATH</b>	<a href="https://www.belart.com/corporate/product-resource-center/certificate-of-analysis/">https://www.belart.com/corporate/product-resource-center/certificate-of-analysis/</a>
<b>CLINIMACS CD34 REAGENT</b>	<a href="https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html">https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html</a>
<b>CLINIMACS CD56 REAGENT</b>	<a href="https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html">https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html</a>
<b>CLINIMACS CD45RA Reagent</b>	<a href="https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html">https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html</a>
<b>CLINIMACS PBS/EDTA</b>	<a href="https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html">https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html</a>
<b>CLINIMACS TUBING</b>	<a href="https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html">https://www.miltenyibiotec.com/us-en/resources.technical-documents/certificates.html</a>
<b>D-PBS</b>	Request on-line from Stem Cell Technologies <a href="http://www.stemcell.com/">http://www.stemcell.com/</a>

STCL-GEN-002 JA1 Certificates of Analysis and/or Certificates of Conformance  
 Stem Cell Laboratory, DUMC  
 Durham, NC

<b>DEXTRAN 40 (IN NACL)</b>	Request by email from <a href="mailto:PICustomerService@pfizer.com">PICustomerService@pfizer.com</a> Request by e-mail from <a href="mailto:info@BioLifeSolutions.com">info@BioLifeSolutions.com</a>
<b>DMSO (STEMSOL)</b>	Included in package, Protide Pharmaceuticals
<b>Origen 50ml FREEZING BAGS</b>	Sign in and request online @ <a href="http://www.origen.com">http://www.origen.com</a>
<b>Origen 250ml FREEZING BAGS</b>	Sign in and request online @ <a href="http://www.origen.com">http://www.origen.com</a>
<b>GAMMUNEX-C (Ivlg)</b>	<a href="mailto:GrifolsMC@dlss.com">GrifolsMC@dlss.com</a>
<b>HEMATOLOGY REAGENT A,B and C</b>	Request online @ <a href="mailto:doccontrol_ebs@elitechgroup.com">doccontrol_ebs@elitechgroup.com</a>
<b>HEMATOLOGY AEROFIX ADDITIVE</b>	Request online @ <a href="mailto:doccontrol_ebs@elitechgroup.com">doccontrol_ebs@elitechgroup.com</a>
<b>6% HETASTARCH in 0.9 SODIUM CHLORIDE(HESPAN)</b>	Request by email <a href="mailto:PICustomerService@pfizer.com">PICustomerService@pfizer.com</a>
<b>HETASEP</b>	Request online from Stem Cell Technologies <a href="http://www.stemcell.com/">http://www.stemcell.com/</a>
<b>25% HUMAN SERUM ALBUMIN</b>	Request by email <a href="mailto:GrifolsMC@dlss.com">GrifolsMC@dlss.com</a>
<b>IMDM</b>	Request on-line from Stem Cell Technologies <a href="http://www.stemcell.com/">http://www.stemcell.com/</a>
<b>LSM (LYMPH SEPARATION MEDIUM)</b>	Print on-line from <a href="http://www.mpbio.com/united_states">http://www.mpbio.com/united_states</a>
<b>METHOCULT 4434</b>	Request on-line from Stem Cell Technologies <a href="http://www.stemcell.com/">http://www.stemcell.com/</a>
<b>OPEN APHERESIS KITS</b>	Online at <a href="http://certificates.freseniuskabiusa.com/Pages/CHome.aspx">http://certificates.freseniuskabiusa.com/Pages/CHome.aspx</a>
<b>PLASMA TRANSFER SETS</b>	Online at <a href="http://certificates.freseniuskabiusa.com/Pages/CHome.aspx">http://certificates.freseniuskabiusa.com/Pages/CHome.aspx</a>
<b>PLASMALYTE A</b>	Request @ <a href="mailto:MPCS_COA_Requests@baxter.com">MPCS_COA_Requests@baxter.com</a>
<b>RPMI-1640 Medium</b>	Request online @ <a href="http://www.thermofisher.com">http://www.thermofisher.com</a>
<b>0.9% SALINE 1000ML</b>	Request by email from <a href="mailto:MPCS_COA_Requests@baxter.com">MPCS_COA_Requests@baxter.com</a>
<b>SAMPLING SITE COUPLERS</b>	Online at <a href="http://certificates.freseniuskabiusa.com/Pages/CHome.aspx">http://certificates.freseniuskabiusa.com/Pages/CHome.aspx</a>
<b>SEPAX WASH KITS</b>	Certificate of Conformance INCLUDED
<b>SEPAX CELL SEPARATION KITS</b>	Certificate of Conformance INCLUDED
<b>STERILE CULTURE WATER</b>	Print on-line from the Sigma Aldrich website <a href="http://www.sigmaaldrich.com">http://www.sigmaaldrich.com</a>

STCL-GEN-002 JA1 Certificates of Analysis and/or Certificates of Conformance  
Stem Cell Laboratory, DUMC  
Durham, NC

<b>STERILE PURIFIED WATER</b>	Included in package from VWR
<b>TC199 MEDIUM</b>	Print on-line from the Sigma Aldrich website <a href="http://www.sigmaaldrich.com">http://www.sigmaaldrich.com</a>
<b>TRANSFER PACK CONTAINERS</b>	Online at <a href="http://certificates.freseniuskabiusa.com/Pages/CHome.aspx">http://certificates.freseniuskabiusa.com/Pages/CHome.aspx</a>
<b>TRICITRASOL</b>	Call 800-299-3411 (certificate of conformance)
<b>TRYPAN BLUE</b>	Print on-line from the Sigma Aldrich website <a href="http://www.sigmaaldrich.com">http://www.sigmaaldrich.com</a>
<b>4 WAY STOPCOCKS (DMSO Resistant)</b>	Sign in and request online @ <a href="http://www.origen.com">http://www.origen.com</a>



**Signature Manifest****Document Number:** STCL-GEN-002 JA1**Revision:** 05**Title:** Certificates of Analysis and/or Certificates of Conformance JA1**Effective Date:** 18 Mar 2022

All dates and times are in Eastern Time.

**STCL-GEN-002 JA1 Certificates of Analysis and/or Certificates of Conformance JA1****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		11 Feb 2022, 06:48:19 PM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		11 Feb 2022, 06:48:35 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		13 Feb 2022, 04:37:21 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch De Gracia (IMS19)		04 Mar 2022, 04:25:49 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		07 Mar 2022, 12:45:08 PM	Approved