

BIOLOGICAL STAIN COMMISSION

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Dear Manufacturer or Vendor representative,

The BSC is recognized around the world as a QC Laboratory specializing in biological stains. The Biological Stain Commission (BSC) has been certifying stains and dyes since 1922. This organization is a non-profit unbiased laboratory designed to certify biological stains for histological use. The BSC certification documentation and certification stickers are looked for by many professionals as a measure of quality in the purchase of reputable biological stains.

In response to your inquiry, this document will outline how to submit your biological stains and dyes to the Biological Stain Commission for testing. Please print this document and use as a guideline. The following pages will help to determining what services are required to establish your powdered material as "BSC Certified" and/or maintain the traceability of your materials' certification status.

Through the course of this guide, if you have any questions or would like to arrange to have your materials Certified, please contact our laboratory at the following:

BSC Laboratory:

Telephone: (585) 275-2751
Fax: (585) 442-8993
e-mail: Chad_Fagan@URMC.Rochester.edu
website: WWW.BiologicalStainCommission.org

WHAT TESTING DO I NEED TO CERTIFY MY LOT OF MATERIAL BY THE BSC?

Some of the first questions that new vendors of stains and dyes have are around identifying the services they require to establish or maintain the certification status of their powder material. The services listed below can guide you on what testing needs to be performed for your material that you possess. The BSC testing laboratory can certify, re-check, or do an experimental on any biological stain based on your needs. You can choose the service you require based on the following:

BSC Service

Criteria

Certification

A certification is submitted when the current material has not been Certified by the Biological Stain Commission and does *not* have a current BSC dye code number in the form of CD-# (where C is the company designation, D is the dye designation and # is the batch of the CD combination). This material has either been purchased from a manufacturer, distributor or manufactured in-house. The certification process will generate a certificate of analysis, coupled with a BSC dye code and vendor lot number for this batch, after the material passes the BSC criteria.

Experimental

An experimental is submitted when the material has either been purchased from another company or manufactured in-house. The current material is *not* Certified by the Biological Stain Commission. The experimental is requested if the material is in question as to its quality and is *not* intended for sale as “BSC Certified”. The results will be reported to the submitting company, however this material will *not* be Certified or recommended for resale by the BSC.

Re-Check

Material that has previously been Certified by the BSC, has a BSC certification dye code and has had a life-cycle event. These events can be summarized as one or more of the following: Sale (or transport) to another company (or facility), new lot number assignment, been repackaged outside of a fill line and/or loss of traceability. As a quality check, a portion of this material is sent to the BSC. The Re-Check verifies that the submitted material has the same identity as the archived BSC Certified material and can be traced to its certificate of analysis. A certificate of analysis will also be provided for the submitted lot and addendum to the BSC Certificate.

WHAT ARE THE FEES FOR THE BSC SERVICES?

Our testing services are itemized accordingly for any service you request from the table below. The certifications are the only service subject to a poundage fee (*). The total poundage fee is the multiple of reported poundage on the certification submittal and the poundage fee below. Labels can only be ordered by companies that possess Certified material which has previously been tested directly through the BSC.

<u>BSC Service</u>	<u>BSC Fees</u>
Certifications	\$500.00
Experimental	\$275.00
Re-Check	\$160.00
Poundage*	\$2.30
Labels (set of 5)	\$5.00
Labels (per sheet of 55)	\$55.00

CHECKLIST TO ORGANIZING YOUR SUBMITTAL TO THE BSC

Certification Submittal Requirements

- Obtain a “full” certification form. This form must be requested directly from the BSC. Be sure to only fill out the top half of the form. The “full” certification form is a 4-page carbon-copy form with a white, yellow, pink and gold sheet. Once complete, separate the gold sheet and retain for your records. Submit the resulting three-page form to the BSC. The yellow sheet will be returned to you as a complete certificate when completed.
- On the certification form fill in the Dye (Name), Date, Name of firm, City and State fields excluding the ‘CODE NUMBER’ field. Check-mark the entry lines asking which samples are enclosed and fill in the lot number of the material. Check the box asking for the origin of the material. Provide the weight of the batch in pounds or kilograms. Please remember to include a signature and date where requested. If a label for the bottles is available, an example can be pasted in the box on the right half way down the form (white page).
- Submit three separate bottles of stain/dye, two of which contain 10-grams of material and one that contains 5-grams of material for archival.
- All bottles must be labeled with company information and specific material lot number.

Experimental Submittal Requirements

- Obtain a “full” certification form. This form must be requested directly from the BSC. Be sure to only fill out the top half of the form. The “full” certification form is a 4-page carbon-copy form with a white, yellow, pink and gold sheet. Once complete, separate the gold sheet and retain for your records. Submit the resulting three-page form to the BSC. The yellow sheet will be returned to you as a complete certificate when completed.
- On the certification form fill in the Dye (Name), Date, Name of firm, City and State fields excluding the ‘CODE NUMBER’ and ‘Weight of Batch’ fields. Check-mark the entry lines asking which samples are enclosed and fill in the lot number of the material. Check the box asking for the origin of the material. Please remember to include a signature and date where requested.
- Submit two bottles of stain/dye, both of which contain 10-grams of material.
- Both bottles must be labeled with company information and specific material lot number.

Re-Check Submittal Requirements

- You may print a copy of the “full” certification form for a re-check, as included in a separate file of this correspondence. The recheck form can also be generated by another form as long as the following fields can be supplied.
- On the certification form, fill in the Dye (Name), CODE NUMBER, Date, Name of firm, City, and State fields. Check-mark the entry lines asking which samples are enclosed and fill in the lot number of the material. Check the box asking for the origin of the material. For the recheck, this information may need to be supplemented to include the life-cycle event justifying the re-check. Please contact the BSC with questions about traceability life-cycle events. Remember to include a signature and date where requested.
- Submit one bottle of stain/dye material with 10-grams.
- Bottle must be labeled with company information, BSC certification code and material lot number.

WHAT ARE THE SHIPPING REQUIREMENTS FOR A TESTING SUBMISSION?

All Material sent to the BSC laboratory for testing have the same shipping and delivery process. The powders shipped must follow all shipping requirements and regulations for the necessary service, including those for hazardous materials when applicable. This may include US, International, and specific shipping carrier service requirements. Please take the time to ensure packages are properly packaged to avoid any delays in delivery. As an example, boxes that are caught up in customs can add several weeks on to the turn-around time.

Specifically, any samples submitted to the BSC must be properly labeled for easy identification. **The bottles of all materials submitted for testing MUST BE LABELLED with company name and material lot number.** Any other information supplied may be at the discretion of the submitting company.

Generally, the BSC requests that powders sent to the laboratory for testing are contained in **amber glass archive bottles**. Other bottles which are not of archive quality, generally will have an effect on the performance of the dye when tested in our laboratory. **Be sure the lids to the bottle(s) during shipping are secured with tape.** When left un-taped, these lids tend to work themselves loose during shipping, which subsequently contaminates the sample. Additionally, place the bottles in a secondary containment barrier (such as a plastic bag) before packaging. Place packaging material around the shipping box so the glass bottle(s) do not come in contact with the package. Place the paper-work separate from the corresponding powder submission in the box, to protect it from cutting or damage during opening of the package.

Mail the package to the following address:

Materials shipped*
Biological Stain Commission
Room B7670
University of Rochester Medical Center
601 Elmwood Avenue
Rochester, NY 14642

**Do not use this address for parcel mail or correspondence.*

HOW DO I PAY FOR THE BSC SERVICES?

Once testing is completed and your order is complete, the BSC will issue an invoice for payment. Payment terms are 90 days from delivery. Payment can be made via a check or electronic ACH transfer (contact the BSC for terms).

Please submit a corporate check made out to the **Biological Stain Commission** to the following address:

Parcel mailings and correspondence
Biological Stain Commission
University of Rochester
Box 626
601 Elmwood Avenue
Rochester, NY 14642

GENERAL INFORMATION FOR BSC PROCEDURES

Certification of dyes are only executed on an individual batch or lot basis. This batch is assigned a distinctive BSC dye code number by the Commission, which includes a reference letter specific for the submitting company. All material tested by the BSC is on permanent file within the Commission Assay Laboratory.

Additional lots of powders may be added to a BSC certification code with the re-check service for any company. This is necessary when a Certified sample has been exposed to a life-cycle event, which compromises the traceability of the Certification status. A re-check (or Recertification) by the BSC reestablishes the traceability required to maintain the Certification status of a stain powder.

Most life-cycle events can be illustrated in Figure 1. The events can both be seen from a direct manufacturer's perspective (above the black arrow) and that of a new vendor, who has acquired a Certified dye from another company (below the black arrow). The dark arrow in the middle of this diagram signifies a Certified dye powder, as intended to be sold to the histological end-user (e.g. clinical laboratory or technician). The light arrows signify life-cycle events that are non-traceable to the BSC. These events can be ameliorated by using BSC testing services (see dark grey arrow in diagram) to reestablish traceability of these powders and recertify them. There are two white arrows which point to a non-certification status. In this case, the powders are used to make solutions for histological use. As these solutions are made from Certified powders, the solutions themselves cannot be Certified by the BSC. However, if the Certification codes and lot numbers are registered with the BSC, it is permitted to claim that "these solutions are made from powders Certified by the BSC".

The time required for testing dyes ranges from 2-6 weeks. When evaluation is completed, a Certificate of analysis will be returned to the company to indicate the results. If the dye has been found satisfactory with confirmed identity, this form will constitute authorization to market the batch as a "Certified Dye."

DYE TESTING AND ASSAY PROCEDURES:

Dyes are tested by different analytical assays and staining procedures. Assay procedures may include spectrophotometric analysis, total dye content by titanous chloride titration, acid precipitation gravimetric procedures, and/or chromatography based on the requirements of each dye. Biological tests are based on staining performance on biological tissues by a variety of procedures in which the dye is most commonly used.

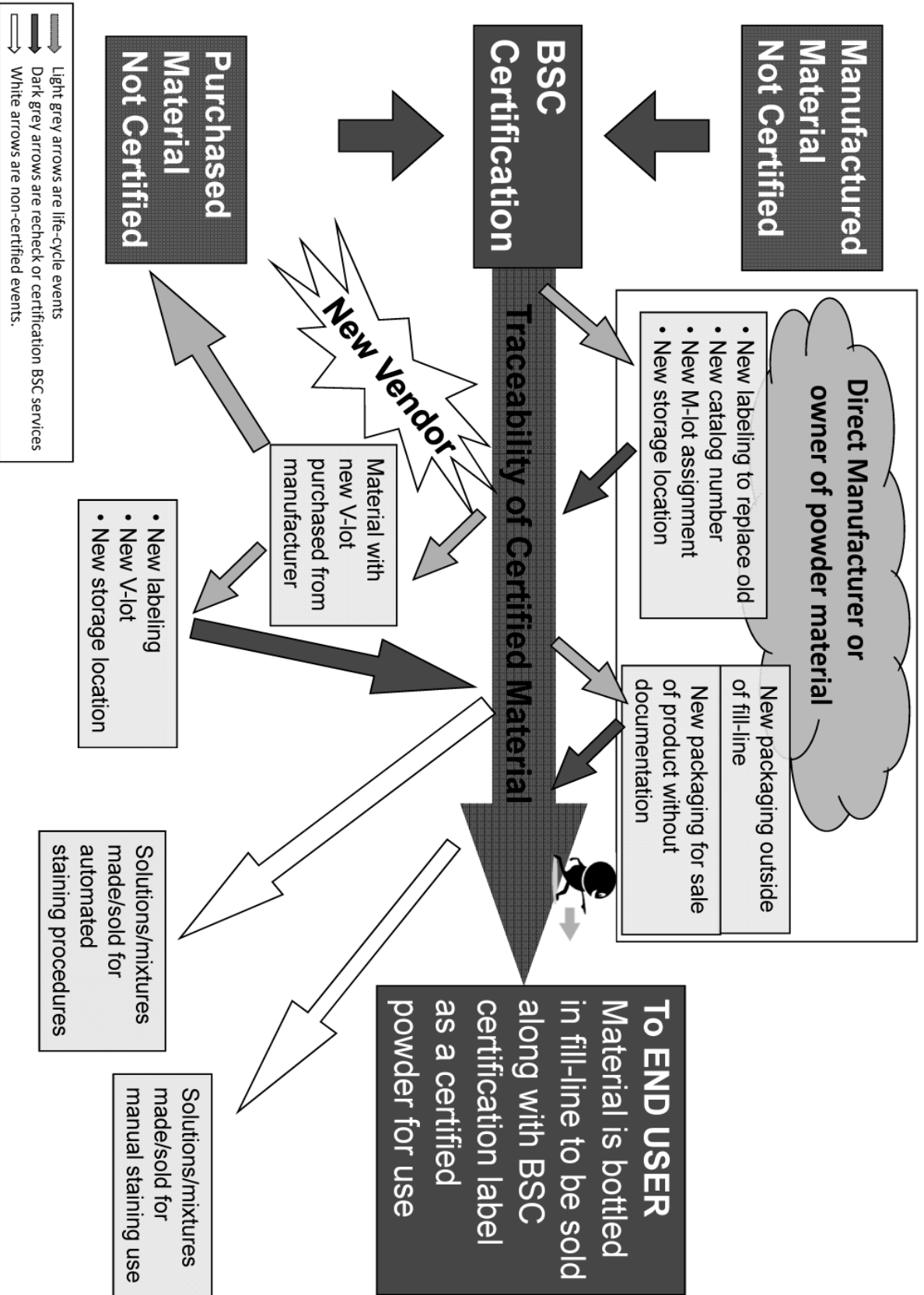
BSC CERTIFICATION LABEL:

Any bottle of dye/stain sold as "BSC Certified" must have a BSC certification label in addition to the company label. A BSC Certification Label is 1" inch high by 1.69" inches wide. The image below illustrates how a BSC Certification Label can maintain traceability on a bottle of Certified material. The lot number for the stain powder on the company label should match the lot number on the BSC Certification Label. These labels are sold to any company who intends to sell BSC Certified powder to end users. Certification label orders can be made at any time by simple correspondence, as long as the requested lot



number is traceable to a BSC Certification code from within the BSC. To complete this requirement, the powdered stain (from the specifying company) must have been previously tested at the BSC laboratory. When ordering labels for Certified dyes, the BSC code and company lot number for the powdered stain must be specified.

Figure 1.
Biological Stain Commission – Certification and Traceability



WHAT STAINS ARE CERTIFIED BY THE BIOLOGICAL STAIN COMMISSION?

The next two pages are a comprehensive list of stains Certified by the BSC.

C.I. Number	Stain	Code	Certified for use in:	% Content
42685	Acid Fuchsin	R	Histology, Andrade Indicator	Yes
74240	Alcian Blue	An	Histology	Yes
58005	Alizarin Red S	Ar	Staining Bone	No
42755	Aniline Blue, W.S	K	Histology	No
41000	Auramine O	Au	Flourescent Microscopy	Yes
50085	Azocarmine G	Ag	Histology	Yes
--	Azure A	Az	Histology, Compounding Of Blood Stains	Yes
52010	Azure B	Ab	Histology, Compounding Of Blood Stains	Yes
--	Azure C	Ac	Histology	Yes
42510	Basic Fuchsin	Fb	Histology, Feulgen Reaction, Bacteriology (Staining) & (Media)	Yes
--	Basic Fuchsin, Flagella	F	Special for Flagella Staining	Yes
21000	Bismarck Brown Y	N	Histology, Bacteriology (Staining)	Yes
51010	Blilliant Cresyl Blue	V	Supravital Staining (Blood)	Yes
42040	Brilliant Green	Bg	Bacteriology (Media Stain)	Yes
75470	Carmine	Ca	Histology	No
30235	Chlorazol Black E	Bc	Histology, Cytology	No
22120	Congo Red	Q	Histology	Yes
--	Cresyl Violet Acetate	Wr	Histology	Yes
42555	Crystal Violet	C	Histology, Cytology, Bacteriology (Media Stain)	Yes
--	Darrow Red	D	Histology	Yes
45400	Eosin B	Eb	Histology	Yes
45380	Eosin Y	E	Histology, Compounding of Blood Stains	Yes
45430	Erythrosin B	Er	Histology	Yes
45386	Ethyl Eosin	Ee	Histology	Yes
42053	Fast Green FCF	Gf	Histology, Cytology	Yes
--	Flourescein Isothiocyanate	Fi	Immunoflourescence	Yes
--	Giemsa Stain	Ge	Blood Staining	No
75290	Hematoxylin	H	Histology, Cytology	No
73015	Indigo Carmine	I	Histology	Yes
11050	Janus Green B	J	Supravital Staining (Blood)	Yes
--	Jenner Stain	Jr	Blood Smear	No

C.I. Number	Stain	Code	Certified for use in:	% Content
42095	Light Green SF Yellowish	L	Histology, Cytology	Yes
42000	Malachite Green	Mg	Histology, Bacteriology (Staining)	Yes
10315	Martius Yellow	Ym	Histology	Yes
42590	Methyl Green	G	Histology, Compounding of Pappenheim Stain	Yes
13025	Methyl Orange	M	Histology	Yes
42535	Methyl Violet 2B	Mv	Histology	Yes
52105	Methylene Blue	A	Histology, Bacteriology Stain, Compounding of Blood Stains	Yes
52041	Methylene Violet	Lv	Compounding of Blood Stains	Yes
60760	Nuclear Fast Red	Nr	Histology	No
50040	Neutral Red	X	Supravital Staining (Blood)	Yes
50420	Nigrosin	Ni	Bacteriology (Staining)	No
51180	Nile Blue A	Nb	Fat Staining	Yes
26125	Oil Red O	Ro	Fat Staining	Yes
15510	Orange II	Ob	Histology	Yes
16230	Orange G	O	Histology	Yes
--	Orcein, Synthetic	Or	Histology, Cytology	Yes
42500	Pararosaniline	Fp	Histology, Feulgen Reaction, Bacteriology (Staining) & (Media)	Yes
45410	Phloxine B	Ph	Histology	Yes
--	Protargol S	Pr	Staining Nervous Tissue	No
45010	Pyronin B	Pb	Histology, Compounding of Pappenheim Stain	Yes
45005	Pyronin Y	Py	Histology, Compounding of Pappenheim Stain	Yes
--	Resazurin	Rz	Testing Reduction in Milk	Yes
45440	Rose Bengal	Rb	Bacteriology (Media Stain)	Yes
50240	Safranin O	S	Histology, Cytology, Bacteriology (Staining)	Yes
26100	Suday III	Y	Fat Staining	Yes
26105	Sudan IV	Z	Fat Staining	Yes
26150	Sudan Black B	Zb	Fat Staining	No
--	Tetrachrome Stain	Mn	Blood Staining	No
52000	Thionin	T	Histology, Staining Frozen Sections	Yes
52040	Toluidine Blue O	U	Histology	Yes
--	Wright Stain	Wr	Blood Staining	No