



21124 Cabot Blvd.
Hayward, California 94545
510-785-2564 Telephone
800-284-4949 Orders
510-782-4639 Fax
www.biolog.com

CERTIFICATE OF ANALYSIS

Product No.: 3440
Name: 65% Turbidity Standard
Lot No.: A111122
Expiration Date: 11 AUG 2024

QUALITY PROFILE

Results

Standard check: 65.0 ± 0.5 % transmittance Passes test

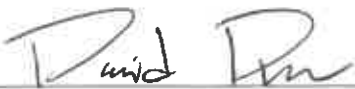
Note: The % transmittance values are obtained from specific reference turbidimeters. These values may differ from turbidimeter to turbidimeter. Reference turbidimeters are calibrated with NIST traceable standards.

STORAGE RECOMMENDATIONS

Store in the dark at 20° - 26°C.

INTENDED USE

NOT FOR HUMAN IN VITRO DIAGNOSTIC USE.


APPROVAL: QUALITY ASSURANCE


DATE

Turbidity Standard, 65%T QC form

LOT # A111122

Turbidimeter

DATE Nov 11 2022

Serial # 11026085

EXPIRATION 11 AUG 2024

TURBIDITY STANDARD, 65%T

% Transmission 65%

STANDARD READINGS

TUBE 1	READING 1	<u>64</u>	_____	_____
	READING 2	<u>65.5</u>	_____	_____
TUBE 2	READING 1	<u>65</u>	_____	_____
	READING 2	<u>66</u>	_____	_____

AVERAGE % T 65.125 _____

(± 0.5 %T)

REPEAT? YES NO YES NO

BIOLOG

65 % T

Turbidity Standard

Catalog No. 3440

Lot No. A111122

Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

N/A w/u/22 DP

RESULTS: Pass

DATE/ TECH 11/11/22 AM

SUPVR *Dwd*
DATE *11/29/22*



TURBIDITY STANDARD MANUFACTURING PROCEDURE, RECORD AND LABEL VERIFICATION

Document revision date: 28Mar12 Prepared by: S.Daugherty/B.So Dept: Mfg/QA

Effective date: Upon approval; Replaces document with effective date: 09Sep08

Approval signature: _____	Department: _____	Date: _____
_____	Research & Development _____	_____
_____	Manufacturing _____	_____
_____	Quality Control _____	_____

LOT# A 111122

DATE 11 AUG 2022 TECH WD

EXPIRATION 11 AUG 2024
(21 months from prep date)

DATE _____ SUPVR _____

Tubes to inventory 50

65% T TURBIDITY STANDARD

% Transmission = 65

1. Prepare 0.005% PLURONIC F68 STOCK (suspension for all Turbidity Standards)

<u>Sigma</u> <u>BCCH0114</u>	<u>.075</u> 0.1 g	PLURONIC F68
SOURCE (vendor/lot#)	<u>2000 ml</u> 2000 ml	PURIFIED H2O
	<u>1500</u>	

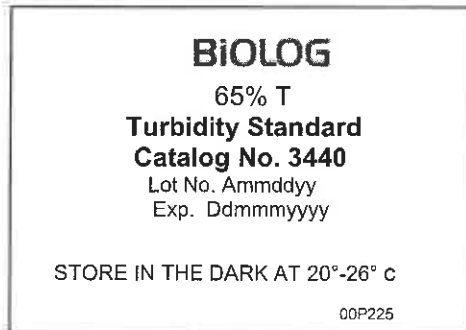
2. To 2 L of 0.005% PLURONIC F68 STOCK, use the appropriate volume of 2.6% POLYBEAD MICROSPHERES.

<u>Poly Sciences</u> <u>A739179</u>	<u>1.2 ml</u> 2.8 ml	Polybead Microspheres 2.6% Solution	<u>1.2 ml</u>
SOURCE (vendor/lot#)	<u>2000 ml</u> 2000 ml 0.005% Pluronic F68 Stock		VOLUME USED
	<u>1050</u>		

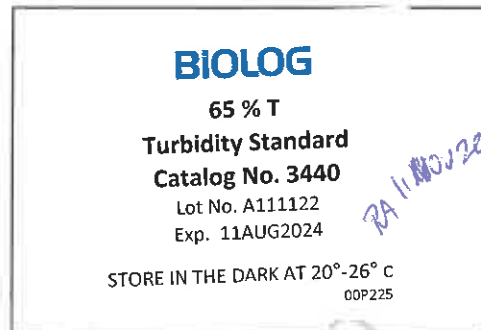
Adjust as necessary to obtain correct % transmission value. 0.09 ml
Additional vol. added (if required)

3. Prepare the following 20 x 150 test tubes for Quality Control testing: 1 Blank tube (suspension)
2 Test standard tubes
4. Obtain Quality Control approval (making adjustments as required by QC personnel.)
5. KEEP STANDARDS LABELED. Dispense approximately 20 ml of each standard into the test tubes, place a rubber stopper and metal cap (crimped) on each.
6. Prepare the appropriate standard label with the LOT# and Expiration Date clearly printed. Carefully align and affix a label on each test tube.

7. LABEL VERIFICATION

LOT# A 111122DATE 11 Nov 2022 PRINTED BY JTEXPIRATION 11 Aug 2024DATE 11 NOV 2022 VERIFIED BY RA

ORIGINAL LABEL



AFFIX LABEL IN THE BOX ABOVE.

Obtain the appropriate number of OL864WS standard label sheets for the batch size (20 labels per sheet).

Prepare the lot specific proof template labels using the ol864.doc (blank) and the 00P 225 65 percent 3440 ol864 templates.

- 1) Copy and paste one cell from the 00P 225 onto the ol864
 - 2) Substitute the correct Lot number and Expiration Date on one cell.
 - a. Lot Number begins with the letter **A** followed by mm dd yy .
 - b. The Expiration Date is 21 months from the date of preparation.
 - 3) Copy and paste into each of the remaining 19 cells.
 - 4) Label must be approved by the printer and verified by an independent person.
 - 5) Affix the approved label to the Label Verification Record.
 - 6) Attach a copy of the full proof sheet of the label for the lot and the Label Verification Record to the Standard Manufacturing Record.
8. Carefully align and affix a label on each test tube, ~1.5 to 2.5 cm below the top of the tube (crimp cap).
 9. Record the final manufactured count on page 1 "Tubes to inventory".
 10. Attach any residual lot specific labels after product labeling and packaging has been completed.
 11. Give a completed manufacturing document copy to QA/QC department.

Revision History:

09 Sep 08-CR/CO # 1352 initial release of "Manufacturing Procedures" (3440).

28Mar2012 CRCO no. 1560: Update label verification page for new label sheets and enhanced instructions.

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225

BIOLOG

65 % T

Turbidity Standard
Catalog No. 3440
Lot No. A111122
Exp. 11AUG2024

STORE IN THE DARK AT 20°-26° C
00P225