

INSTRUMENT VALIDATION AFTER REPAIR

VALIDATION AFTER REPAIR

It is required that all instruments be validated after any repair before they are used for performing tests.

The following procedure will be followed in the Orange County Area Laboratories when an instrument has been repaired in the laboratory by service personnel or if an instrument has been sent out for repair.

Steps	Action
1	The Instrument will be calibrated according to the procedure for that instrument, if calibration is required.
2	The controls required by the instrument procedure will be run.
3	The control results will be evaluated according to the laboratory quality control program.
4	If the controls do not meet the required criteria, the instrument cannot be placed into service and a supervisor must be notified.
5	If the controls meet the required criteria the instrument can be placed into service.
6	The service repair report must then be placed in the PM log book.

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Controlled Documents

The following controlled documents support this procedure.

Reference
1. Sysmex Product Notification Document Number: 62-1539: XN-L Series™: BeyondCare Quality Monitor and Calibration Verification
2. Sysmex XN-L Series XN-550/XN-450/XN-350 Basic Operation (North American Edition), Sysmex Corporation, Kobe, Japan.
3. Sysmex XN-L Series XN-550/XN-450/XN-350 General Information (North American Edition), Sysmex Corporation, Kobe, Japan.
4. Sysmex XN-L Series XN-550/XN-450/XN-350 Troubleshooting (North American Edition), Sysmex Corporation, Kobe, Japan.
5. Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).
6. Sysmex Reagents of America Inc., Mundelein, IL. XN CAL, Hematology Calibrators: Calibrators for Sysmex Hematology XN-L Series Analyzers, package insert.
7. Sysmex America Inc., Lincolnshire, IL. XN-L CHECK Hematology Control for Sysmex XN-L Series Analyzers package insert.
8. Sysmex Reagents of America, Inc. SDS sheets and reagent product inserts.
9. Sysmex America Inc., Lincolnshire, IL. XN-L Applications Manual.
10. CLIA Brochure 3, “Calibration and Calibration Verification” (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6065bk.pdf) Accessed April 10, 2019.
11. US Code of Federal Regulations, Title 42, Chapter IV, Subchapter G, §493.2 (Definitions).

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Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Director of Lab Ops. reviewed/ date	Date change Implemented
MINOR	1. Regional Template Update 2. Revised index no.	Yvette Lingat 4/17/2020		Mary Lou Beaumont	4/28/2020