Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0180295	06/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Hospital	401 E Murphy Ave Floor #1, Connellsville, PA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of Laboratory procedure manuals and interview with the technical consultant (TC), the laboratory failed to establish a complete competency assessment procedure to assess the competency of testing personnel (TP) who performed Microbiology, Chemistry, Hematology, Immunohematology, Serology, Parasitology, Toxicology, Urinalysis tests and for consultants in 2018. Findings Include: 1. On the day of survey, 06/18/2019, the laboratory failed to provide a complete written policy on how to assess the competency of testing personnel (TP) who Microbiology, Chemistry, Hematology, Immunohematology, Serology, Parasitology, Toxicology, Urinalysis tests and for consultants. 2. The laboratory could not provide competency assessment records for the following personnel in 2018: - 1 of 1 Initial 6 month competency for TP#13. - 12 of 13 TP who performed Microbiology, Chemistry, Hematology, Immunohematology, Serology, Parasitology, Toxicology, Urinalysis tests. - 1 of 1 TC / general supervisor. 3. In 2018, 514,165 patient tests were analyzed. 4. The TC confirmed the findings above on 06/18/2019 around 09:00 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification (Cal Ver.) records and interview with the technical consultant (TC), the laboratory failed to perform cal. ver. on 2 of 2 Beckman Coulter AU680 analyzers and on 1 of 1 Siemens Rapid Point 500 analyzer, once every 6 months in 2018. Findings include: 1. On the day of survey, 06/18/2019, the TC could not provided documentation of cal. ver. performed on 2 of 2 Beckman Coulter AU680 analyzers and 1 of 1 Siemens Rapid Point 500 analyzer performed every 6 months in 2018. 2. In 2018, 339, 125 specimen were analyzed on the Beckman Coulter AU680 analyzers. 3. In 2018, 1,820 specimen were analyzed on the Siemens Rapid Point 500 analyzer. 4. The TC confirmed the finding above on 06/18/2019 around 02:30 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the technical consultant (TC), the laboratory failed to document QC procedures each day of patient testing for 7 of 7 Wet Mount microscopic examinations, 1129 of 1129 erythrocyte sedimentation rate (ESR) tests performed on the Polymedco Sedimat 15 Plus Automated Sedrate analyzer and 378 of 378 Clostridium difficile (C. diff) tests performed on the Alere C. diff Quik Check Complete kits from 2018 to the date of survey. Findings Include: 1. On the day of survey, 06/18/2019, review of quality control records revealed the laboratory did not document QC procedures performed each day of patient testing for 7 of 7 Wet Mount microscopic procedures, 1129 of 1129 ESR tests and 378 of 378 c.diff tests from 2018 to 06/18/2019. 2. In 2018, 5 Wet Mount Microscopic Examination were analyzed. 3. In 2019 (01/01/2019 to 06/18 /2019), 2 Wet Mount Microscopic Examination were analyzed 4. In 2018, 828 ESR tests were analyzed. 5. In 2019 (01/01/2019 to 06/18/2019), 401 ESR tests were

	analyzed. 6. In 2018, 2030 c. diff tests were analyzed. 7. In 2019 (01/01/2019 to 06/18/2019), 980 c. diff tests were analyzed 8. The TC confirmed the findings above on 06/18/2019 around 01:00 pm.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory failed to document visual inspection on each lot/shipment of BioMrieux Chromogenic Medium Identification (CHROMID) methicillin-resistant Staphylococcus aureus (MRSA) Culture Media used for throat culture screens from 10/17/2017 to the date of survey. Findings include: 1. On the day of survey, 06/18/2019, the TC could not provided documentation of visual inspection performed on each lot/shipment of the BioMrieux CHROMID MRSA culture media received from 10/17/2019 to 06/18/2019. 2. The TC confirmed the finding above on 06/18/2019 around 11:45 am.