Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188647	04/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pshmg - Lime Spring	2221 Noll Drive, Lancaster, 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: A. Based on review of the laboratory competency assessment records and interview with the Technical Consultant #1 (TC1), the laboratory failed to establish a complete procedure to assess the competency assessment of 2 of 5 testing personnel (TP) (on the CMS 209 form, listed as personnel #3 and #5) who analyzed urine cultures and throat cultures from 01/01/2020 to 12/31/2020. Findings include: 1. On the day of survey 04/29/2021 at 09:08 a.m., the TC1 could not provide a complete competency assessment policy to assess 2 of 5 TP for the six points of CLIA from 06/27/2019 to the day of survey. 2. Review of the competency assessment records for 2 of 5 TP revealed the laboratory did not document proficiency testing or blind sampling for urine cultures and throat cultures from 01/01/2020 to 12/31/2020. 3. The TC1 confirmed the findings above on 04/30/2021 at 13:15 B. Based on review of laboratory procedure manuals and interview with the Technical Consultant (TC) #1, the laboratory failed to establish a complete competency assessment procedure to assess the competency of 2 of 2 Technical consultants for their regulatory responsibilities from 06/27/2019 to the date of survey. Findings Include: 1. On the day of survey 04/29/2021 at 09:30 a.m., the laboratory could not provide a written procedure to assess the competency assessment of 2 of 2 TC for their regulatory responsibilities from 06/27/2019 to the day of survey. 2. The TC1 confirmed the finding above on 04/29/2021 at 09:35 am.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the urine culture procedure and interview with the Technical Consultant (TC)#1, the urine culture written procedure manual did not include all quality control (QC) requirements applicable for the urine culture media from 06/27 /2019 to the day of survey. Findings include: 1. On the day of survey 04/29/2021 at 10: 17 a.m. review of the urine culture procedure manual revealed the QC section did not include the performance of QC for the Orion uricult media's ability to support growth for each batch/lot/shipment from 06/27/2019 to the day of survey. 2. The TC 1 confirmed the finding above on 04/29/2021 at 13:10.