Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1035679	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pshmg-Lime Spring Outpatient Center	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the Technical Supervisor (TS) #1, the Laboratory Director (LD) failed to sign the API PT attestation statement documents from 2019 and 2020. Findings include: 1. On the day of survey, 09/25/2020, review of API PT records revealed, the following API PT attestation statement documents were not signed by the LD: - 2019, Event #1, Event #2, and Event #3: Hematology/coagulation. - 2020, Event #1 and Event #2: Hematology/coagulation - 2020, Event #1: Miscellaneous Chemistry. 2. The TS #1 confirmed on 09/25/2020 at 12:10 p.m. the findings above.
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 lack of competency assessment records and interview with the Technical Supervisor (TS) #1, the Laboratory failed to assess the competency of 1 of 3 testing personnel (TP) (on the CMS-209 form listed as testing personnel 1) who performed tests in the specialities of Hematology, Coagulation, Chemistry, and Urinalysis for

	2018, 2019, and 2020 Findings include: 1. On the day of survey, 09/25/2020, the TS could not provide competency assessment records for TP #1 from 07/12/2018 to the date of survey. 2. The Technical Supervisor confirmed the finding above on 09/10 /2020 at 12:15 p.m.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of i-STAT Protime (PT)/INR policy, review of Quality Control (QC) records and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform two control materials of different concentrations each day of patient testing for i-STAT PT/INR cartridge in 2019 and 2020. Findings include: 1. The i-STAT Protime/INR policy states, "Liquid QC is performed monthly". 2. On the day of survey, 9/25/2020, review of i-STAT PT/INR QC records revealed, the laboratory did not perform two levels of control material each day of patient testing for the i-STAT Protime/INR tests analyzed in 2019 and 2020. 3. In 2019, 50 PT/INR tests were analyzed. 4. In 2020 (01/01/2020 to 09/25/2020), 34 PT/INR tests were analyzed. 5. The TS #1 confirmed the findings above on 09/25/2020 ay 10:45 am.
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 lack of urine sediment microscopic examination quality control (QC) records, review of Urine Microscopic Procedure, and interview with Technical Supervisor (TS) #1, the laboratory failed to perform QC each day of patient testing for urine microscopic examinations from 2019 to the day of survey. Findings Include: 1. The Urine Microscopic Procedure (page 4) point 8 stated : "Quality Control: Not applicable". 2. In 2019, 144 urine microscopic examinations were analyzed. 3. In 2020 (01/01/2020 to 09/25/2020), 118 urine microscopic examinations were analyzed. 4. The TS #1 confirmed on 09/25/2020 around 11:15 am, that QC was not performed for urine microscopic examinations from 01/01/2019 to 9/25/2020.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the General Oversight Procedure, review of the laboratory General Oversight Report records and interview with Technical Supervisor (TS) #1, The laboratory failed establish a General oversight procedure in January of 2019 and follow the General oversight procedure for 4 of 9 months in 2020. Findings include: 1. The laboratory's General Oversight Procedure (page 4) under frequency states: " The Medical Director and Laboratory Manager shall meet: At least one time per month" was establish in May of 2019. 2. On the day of survey 09/25/2020, review of the General Oversight Procedure revealed, patient testing began on January 2019 and the policy was not established until May of 2019. 3. Review of the General Oversight Report records revealed, the General Oversight Reports were not documented for 4 out of 9 months in 2020 (February, March, May, and July). 4. The TS #1 confirmed the findings above on 9/25/2020 at 12:15 p.m.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) Proficiency Testing (PT) records and interview with Technical Supervisor (TS) #1, the laboratory director did not ensure that an approved, effective corrective action plan was documented for the unsatisfactory results for API 3rd event Hematology/Coagulation cellular identification in 2018. Findings include: 1. On the day of survey, 9/25/2020, review of API PT records revealed, the laboratory did not document a correction plan for the 2018 event 3 Cell ID/ or WBC Differential with score of 20%. 2. The TS #1 confirmed the finding above on 9/25/2020 at 12:20 p.m.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A

	laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Director (LD) and the Technical Supervisor (TS) #1, the laboratory failed to have information and data needed by surveyors to make a determination of the laboratory's compliance with Mohs and KOH testing perform onsite from 12/14/2018 through the date of survey. Findings Include: 1. On the date of survey, 9/25/2020, the surveyors requested the following documentation from 12/14/2018 to 9/25/2020: - Competency assessment documentation for 4 of 7 TP. - Competency assessment documentation for 1 of 2 TS. - KOH procedure manual. - KOH Quality Control records. - KOH Proficiency testing/peer review records. - KOH final reports and requisitions. - A complete Mohs procedure manual. - Mohs Quality Control records. - Mohs Proficiency testing/peer review records. - Mohs maps and final reports. - Quality Assessment records for Mohs and KOH. - 2018 and 2019 room temperature records. - 2018 and 2019 cryostat temperature records. 2. The LD and TS #1 could not provide the requested documents at the time of inspection (09/25 /2020 at 12:25). *** KOH = Potassium hydroxide