

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2150107	(X3) Date Survey Completed 04/04/2023
Name of Provider or Supplier Kissel Hill Urgent Care	Street Address, City, State 51 Peters Road, Suite 101, Lititz, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) Proficiency Testing (PT) records and interview with technical consultant (TC)#1 and #2, the laboratory failed to test 5 of 5 AAFP PT events with the laboratory's regular patient workload by personnel who routinely performed the testing in the laboratory in 2021 and 2022. Findings include: 1. On the day of survey, 04/04/2023 at 09:30 am, review of the attestation statements revealed that samples from 2 of 2 AAFP PT events were only tested by 1 of 15 testing personnel (CMS 209 TP#2) in 2021 and 3 of 3 AAFP PT events were only tested by 1 of 15 testing personnel (CMS-209 TP#1) in 2022. 2. TC#1 and TC#2 confirmed the finding above on 04/04/2023 around 11:30 am.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with technical consultant (TC)#1 and #2, the laboratory failed to establish written policies and procedures to assess the competency of 1 of 1 clinical consultants (CC) and 2 of 4</p>

	<p>technical consultants (TC) for their supervisory responsibilities from 03/22/2021 to the date of the survey. Findings include: 1. On the day of the survey, 04/04/2023 at 10:25 am, the laboratory could not provide a written procedure to assess the competency of 1 of 1 CC (CMS 209 personnel # 2) and 2 of 4 TC (CMS 209 personnel #3, and #18) for their supervisory responsibilities from 03/22/2021 to 04/04/2023. 2. The laboratory could not provide competency assessment records for 1 of 1 CC in 2021 and 2 of 4 TC (TC#1 in 2021 and TC#4 in 2021 and 2022) for their supervisory responsibilities. 3. TC#1 and TC#2 confirmed the finding above on 04/04/2023 around 11:30 am.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical consultant (TC)#1 and #2, the laboratory failed to document a negative and positive control material each day of patient testing for KOH and Wet Prep microscopic examinations from 03/22/2021 to the date of the survey. Findings include: 1. On the day of survey, 04/04/2023 at 10:06 am, the laboratory could not provide documentation of daily quality control performed for KOH and Wet mount microscopic examinations from 03/22/2021 to 04/04/2023. 2. The laboratory performed 17 KOH and Wet mount microscopic examinations in 2022 (annual volume listed on CMS 116 form). 3. TC#1 and TC#2 confirmed the finding above on 04/04/2023 around 11:30 am. * This is a repeat deficiency.</p>
<p>D5463</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g)</p> <p>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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the technical consultant (TC)#1 and #2, the laboratory failed to over time rotate control material testing between 8 of 9 testing personnel (TP) who perform chemistry testing on the iSTAT instrument from 03/22/2021 to the date of the survey. Findings include: 1. On the date of the survey, 04/04/2023 at 10:10 am, review of the quality control documents for the iSTAT instrument revealed that 8 of 9 TP (CMS 209 TP# 1,3,4,5,6,7,8, and 15) did not perform QC from 03/22/2021 to 04/04/2023 for chemistry testing performed on the iSTAT instrument. 2. TC#1 and TC#2 confirmed the finding above on 04/04/2023 around 11:30 am.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES</p>

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

A. Based on review of competency assessment records and interview with technical consultant (TC) #1 and #2, the TC failed to evaluate and document the performance of 4 of 6 testing personnel (TP) responsible for performing Potassium Hydroxide (KOH) and Wet Mount microscopic examinations for their annual competency in 2022. Findings include: 1. On the day of survey, 04/04/2023 at 10:30 am, the laboratory was unable to produce the annual competency assessment records for 4 of 6 TP (CMS 209 TP #11,12,13, and 14) that performed KOH and Wet Prep slide examinations. 2. The laboratory performed 17 mycology/parasitology tests in 2022. 3. TC #1 and #2 confirmed the above findings 04/04/2023 around 11:30 am. B. Based on review of competency assessment records and interview with technical consultants (TC) #1 and #2, the TC failed to evaluate and document the performance of 1 of 9 testing personnel (TP) responsible for performing chemistry and hematology examinations on the iSTAT analyzer for their semi-annual competency from March 2022 to the day of survey. Findings include: 1. On the day of survey, 04/04/2023 at 10:30 am, the laboratory was unable to produce the semi-annual competency assessment records for 1 of 9 TP (CMS 209 TP #4) that performed chemistry and hematology examinations using the iSTAT analyzer from March 2022 to April 2023 . 2. The laboratory performed 1432 chemistry and hematology examinations in 2022. 3. TC #1 and #2 confirmed the above findings 04/04/2023 around 11:30 am.