Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2267785	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Calumet Quick Care Ltd	5518 Calumet Ave, Hammond, IN	

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
D0000	A complaint survey was completed on 2-17-2025. The following condition-level deficiencies were found to be out of compliance: D2000-42 CFR. 493. 801 Condition: Enrollment and testing of samples D8100- 42 C.F.R. 493.1771 Inspection requirements applicable to all CLIA certified and CLIA-exempt laboratories
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, interview and record review, the laboratory performed testing outside their certificate of waiver testing for five of five analytes [influenza A and B (Flu A/B) and respiratory syncytial virus (RSV), Coronavirus-19 (CoV-2), and streptococcus A (strep A)] using the analyzer, Cepheid GeneXpert categorized by the Food and Drug Administration (FDA) as moderate complexity from July 26 2023 to February 2025 and seven (Pt#1-Pt#7) of seven patients reviewed. Findings include: 1. During a tour on 2-17-2025 at 11:40 am, a Cepheid GeneXpert (SN: 120000020) analyzer was observed. An opened box of "Xpert Xpress CoV-2 FluRSV plus", LOT#: 100145373 received date 1/22/2025 was on a shelf in the laboratory. 2. An online review of the FDA database confirmed the Cepheid GeneXpert System as moderate complexity for the analytes influenza A/B (Flu A/B) and respiratory syncytial virus (RSV), Coronavirus-19 (CoV-2), and streptococcus A (strep A). 3. In an interview on 2-17-2025 at 1:30 pm, SP-01 indicated that 100 patients were tested on the GeneXpert analyzer since 2023. 4. During a second tour of the laboratory on 2-17-2025 at 1:35 pm, review of the patients tested on the GeneXpert Cepheid System identified the last patient (Pt#1) test sample was analyzed on 2-4-2025 for CoV-2, Flu A/B, RSV and Strep A. 5. In an interview on 2-17-2025 at 1:40 pm, SP-01 (testing

	personnel) confirmed they started installation for the Cepheid GeneXpert analyzer on 6-1-2023. 6. A total of seven patients were reviewed from medical records and the GeneXpert analyzer and showed testing performed from 7-26-23 to 2-4-2025: a. Pt#1 was tested on 2/4/2025 for CoV-2, RSV, Flu A/B, and strep A. b. Pt#2 was tested on 12/6/2024 for Cov-2, Flu A/B, RSV and strep A. c. Pt#3 was tested on 11/29/2024 for CoV-2, Flu A/B, and RSV. d. Pt#4 was tested on 11/7/2024 for strep A. e. Pt#5 was tested on 10/24/2024 for strep A. f. Pt#6 was tested on 10/11/2024 for CoV-2, Flu A /B, RSV. g. Pt#7 was tested on 7-26-2023 for CoV-2, Flu A/B, RSV and strep A. 7. Annual Test volume for the Cepheid GeneXpert testing is 100 tests per year.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, interview and record review, the laboratory failed to enroll in Proficiency Testing (PT) program in the specialty of virology for four of five moderate complexity analytes [Influenza A, Influenza B (flu A/B), Respiratory Syncytial Virus (RSV) and Streptococcus A (strep)] tested using the GeneXpert system from July 2023 to February 4, 2025. Findings Include 1. During a tour on 2-17-2025 at 11:40 am, a Cepheid GeneXpert (SN: 120000020) analyzer was observed in the laboratory. 2. Upon request for proficiency testing documentation from 2023 to 2025 on 2-17-2025 at 11:45 am, SP-01 (testing personnel) indicated the laboratory had not enrolled in proficiency testing from that time period. SP-01 was not able to provide any documentation for PT enrollment for the years 2023, 2024 and 2025 for moderate complexity analytes [Influenza A, Influenza B (flu A/B), Respiratory Syncytial Virus (RSV) and Streptococcus A (strep)]. 3. Seven of seven patient records reviewed had test samples ran on the GeneXpert analyzer from July 2023 to February 2025 without proficiency testing enrollment. Refer to D1001. 4. Annual Test volume for the Cepheid GeneXpert testing is 100 tests per year.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 (a) Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. (b) All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on record review, observations and interview, the laboratory performed Moderate Complexity testing outside the certificate of waiver testing five of five analytes (influenza A and B (Flu A/B) and respiratory syncytial virus (RSV),

	Coronavirus-19 (CoV-2), and streptococcus A (strep A) tested using the analyzer, Cepheid GeneXpert and categorized by the Food and Drug Administration (FDA) as moderate complexity from July 26 2023 to February 2025 and seven (Pt#1-Pt#7) of seven patients reviewed.. (Refer to D8201).
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on record review, observations and interview, the laboratory performed Moderate Complexity testing outside the certificate of waiver testing five of five analytes (influenza A and B (Flu A/B) and respiratory syncytial virus (RSV), Coronavirus-19 (CoV-2), and streptococcus A (strep A) tested using the analyzer, Cepheid GeneXpert and categorized by the Food and Drug Administration (FDA) as moderate complexity from July 26 2023 to February 2025 and seven (Pt#1-Pt#7) of seven patients reviewed. (Refer to D8201).