Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2154451	11/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bchp Infusion Center	19 Bradhurst Ave Suite 800, Hawthorne, NY	

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	An announced Clinical Laboratory Improvement Amendments (CLIA) exempt-state validation survey was conducted at the BCHP Infusion Center on November 6, 2023, by a Centers for Medicare & Medicaid Services (CMS) New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA exempt-state validation survey performed on November 6, 2023.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1, the laboratory failed to ensure a corrective action plan was documented for the unacceptable second API PT Hematology event in 2023. Findings Include: 1. The Testing and evaluation of PT samples, standard operation procedures , Procedure notes and Limitations B. Unacceptable results under a states, "Investigation of unacceptable PT performance will be conducted and event report generated". 2. On the day of survey, November 6, 2023, the laboratory was unable to provide corrective action documentation for the API PT Hematology event #2 in 2023 for: - 60% MCV. - 60% Monocytes. 3. The laboratory was given until the end of the day November 6, 2023 to provide corrective

	action documentation. 4. On November 7, 2023 TP#1 confirmed via email and phone that a corrective action was not documented for the unacceptable event in 2023.
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 a review of the laboratory personnel competency assessment records and an interview with testing personnel (TP) #1, the laboratory failed to establish written policies and procedures to assess one of one technical consultant (TC) for competency in 2021 and 2022. Findings Included: 1. The Laboratory Personnel Report (Form CMS-209) signed by the laboratory director on November 6, 2023 lists one TC for the laboratory. 2. On the day of survey (November 6, 2023), review of the BCHP staff training policy, revealed, that the laboratory did not establish a policy to assess the competency assessment of a TC for their supervisory responsibilities. 3. Interview with TP#1 on November 6, 2023 at 10:30 am confirmed the laboratory did not establish a written policy to assess the TC for competency.
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 a review of laboratory procedures and an interview with testing personnel (TP) #1, the laboratory failed to include in the Horbia Pentra 60 C + procedures on how to document corrective actions to take when quality control results fail to meet the laboratory's criteria for acceptability for the Horbia Pentra 60 C + analyzer used for complete blood count (CBC) testing from 2021 to the day of survey. Findings Include: 1. A review of a sampling of the Horbia Pentra 60 C + analyzer QC print outs from 2023 on November 6, 2023 revealed: - March 14, 2023 - the high control

	(PX440H) was run seven times (Red Blood Cells were low) until the QC passed. - May 1, 2023 - the high control (PX440H) Monocyte % and Monocyte # were high. - July 19, 2023 - the high control (PX440H) hemocrit was high. - October 3, 2023 - hemoglobin was low. 2. The laboratory was unable to provide documented corrective actions taken for the above QC failures. 3. TP#1 confirmed on November 6, 2023 at 12:30 pm that the laboratory did not have documentation for corrective actions take for failed QC or have a procedure in place that included how to document corrective actions to take when quality control results fail to meet the laboratory's criteria for acceptability for the Horbia Pentra 60 C + analyzer.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of laboratory temperature records and an interview with testing personnel (TP) #1, the laboratory failed to document corrective actions taken for out of range refrigerator temperatures in 2022 and 2023. Findings Include: 1. Review of refrigerator temperature records (Fridge - Tag 2L #160500069518) stated the follow temperature errors in 2022 and 2023: - Arpil 4, 2022 - Sensor Connection Error. - February 18, 2023 to February 20, 2023 - Upper alarm limit (lasted 3 days). - May 2, 2023 - Sensor Connection Error. - July 22, 2023 - Upper alarm limit (lasted 13 hours). - July 26, 2023 - Sensor Connection Error. 2. The laboratory was unable to provide correction action documentation for temperature out of range and for Sensor Connection Error on November 6, 2023. 3. TP#1 confirmed on November 6, 023 at 11:15 am that corrective actions were not documented for the above refrigerator errors.