Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1037139	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Badia Medical Llc Dba Lifeguard Pediatrics	107 Peacock Drive, Warner Robins, GA	

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 initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on December 16, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following condition and standard level deficiencies were cited:
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 the lack of Proficiency Testing (PT)documentation and staff interview the laboratory had failed to enroll in a proficiency testing (PT) program for the Abbott Cell-Dyn 1700 Hematology Analyzer. The Laboratory has volunteered to stop testing using the Abbott Cell-Dyn 1700 Hematology Analyzer until two successful PTscores have been received. Reference: D6015
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 review of the personnel files, and staff interview five of five testing personnel listed on the CMS 209 Laboratory Personnel Report, did not have initial or 6 month competencies performed. The competency must cover the six required criteria to be acceptable. Findings: 1. Competency documents were not available for the initial or 6 month review for five out of five testing personnel listed on the CMS 209 form titled Laboratory Personnel Report. The competency documents must cover the six required criteria 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records; 4. Direct Observations of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing preciously analyzed specimens, internal blind testing samples or external PT samples; and 6. Assessment of problem solving skills. 2. Interview with staff #1 (CMS 209 form) and the office manager, on December 16, 2020, at approximately 2:45 PM, in the laboratory area confirmed that there were no competency documents for five out of five testing personnel listed on the CMS 209 form.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration documents for the Cell-Dyn 1700 (CD1700) Hematology Analyzer and staff interview, the laboratory failed to provide documentation that the CD1700 had been calibrated every 6 months, since 10/7/2019. Findings: 1. Review of the CD1700 calibration documents confimed that calibration for the CD1700 was performed October 17, 2019. There were no other documents to review. 2. Interview

	with staff #1 (CMS 209 form) and the office manager on 12/16/2929, at approximately 2:30 pm , confirmed there were no other calibrations documents after October 17, 2019.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing Documentation and staff interview the laboratory director failed to ensure that the laboratory was enrolled in an HHS approved Proficiency Testing program for the Abbott Cell-Dyn 1700 Hematology Analyzer. Findings: 1. The laboratory did not have any documentation for an HHS approved Proficiency Testing program for the Abbott Cell-Dyn 1700 Hematology Analyzer. 2. Interview with staff #1 (CMS 209 form), the office manager, and the LD on December 16, 2020, at approximately 3 PM, in the lab area, confirmed that they laboratory was not enrolled in a HHS approved Proficiency testing program for the Abbott Cell-Dyn 1700 Hematology Analyzer
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Control documents from November 2019 to November 2020 the Abbott Cell-dyn 1700 (CD1700) Hematology Analyzer and staff interview, the laboratory failed to run the three levels of QC each shift of patient testing. Findings: 1. Review of the QC documents for the CD1700 showed that out of 135 Complete Blood Cell Counts (CBC) 51 were ran with no QC on the day of testing for the last 12 months. 2. Interview with staff #1 (CMS 209 form), Office Manager, and the Laboratory Director, on December 16, 2020 at approximately 2:50 PM in the lab area, confirmed the aforementioned finding.