Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0982365	02/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ballad Health Medical Assoc Peds Of Greeneville	1406 Tusculum Blvd Suite 1200, Greeneville, TN	

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
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 the lack of a procedure manual for performing Complete Blood Count (CBC) testing and interviews with the Primary Testing Person and Technical Consultant. it was determined the laboratory failed to have a procedure manual for pre-analytic, analytic and post-analytic processes for CBC testing for review on 2/11/2020. The findings include: 1. There was no procedure manual for CBC testing to include pre-analytic, analytic and post-analytic processes for review on survey date 2/11/2020. 2. Interviews at approximately 2:00 p.m. on 2/11/2020 with the Primary Testing Person and Technical

	Consultant confirmed there was no procedure manual for performing CBC testing available for review. ==========
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 a review of the Laboratory's Calibration Verification records for the Hematology analyzer and upon interview with the Primary testing person, it was determined the laboratory failed to ensure that calibration verification was performed at six month intervals for 2018. The findings include: 1. A review of Calibration Verification records for the hematology analyzer revealed calibration verification not documented in 2018. 2. An interview with the Primary Testing Person at approximately 2:00 p.m. on 2/11/2020 confirmed there was no calibration verifications documented for the Hematology analyzer for 2018. ==========
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: ========== Based on review of patient number

	####5527 manually entered CBC report on 1/02/2020, CBC instrument printout, no system for manual entry review and interviews with the Primary Testing Person and Technical Consultant, determined the laboratory failed to ensure the test results were accurately entered into the patient electronic medical record (EMR). The findings include: 1. A review of patient number ####5527 manually entered CBC report on 1 /02/2020 revealed the Granulocyte # was manually entered into the EMR as 6.3 K/ul. 2. A review of the patient number ####5527 CBC instrument printout on 1/02/2020 revealed the Granulocyte # to be 5.3 K/ul. 3. Interviews on 2/11/2020 at 2:00 p.m. with the Primary Testing Person and Technical Consultant confirmed the Granulocyte was manually entered into the EMR incorrectly for patient number ####5527 and there was no system in place to ensure accurate entry of manual test results. ==========
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 a review of the unacceptable scores for the 3rd event of 2019 Hematology Proficiency Testing (PT) results, lack of corrective action for unacceptable results and upon interviews with the Primary Testing Person and Laboratory Director, it was determined the Laboratory Director failed to ensure that corrective action was documented for unacceptable results. The findings include: 1. A review of the 3rd event of 2019 Hematology PT results revealed unacceptable scores for Erythrocyte Count (20% score), MCH (40% score), MCV (0%) and White Blood Cell (WBC) Auto Differential (40% score). 2. There was no corrective action documented for the unacceptable PT results for the 3rd event of 2019 Hematology and was signed by the Laboratory Director. 3. Interviews at approximately 2:00 p.m. on 2/11/2020 with the Primary Testing Person and Laboratory Director confirmed there were unacceptable PT scores for the 3rd event of 2019 with no corrective action documented. ==========
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: ========== Based on the lack of training documented for the new laboratory testing person for performing Complete Blood Counts (CBC's) hired 12/09/2019, and upon interviews with the Primary Laboratory Testing Person and Laboratory Director, determined the laboratory failed to document training for the newly hired lab testing person to include preanalytical, analytical and postanalytical phases of testing, prior to reporting out patient CBC results. The findings include: 1. There was no documentation of training for CBC testing for new laboratory testing person to include preanalytical, analytical and postanalytical phases of testing prior to reporting patient CBC results, since hire date of 12/09/2019. 2. Interviews with the Primary Laboratory Testing Person and Laboratory Director at approximately 2:00 p.m. on February 11, 2020 confirmed documentation of training for the new testing personnel performing CBC's prior to reporting patient CBC results. ==========
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: ========== Based on documentation on 2/11 /2020 of a Technical Consultant on the CMS-209 Laboratory Personnel Report Form (CLIA) and upon interviews with the Laboratory Director and Technical Consultant, there were no written responsibilities and/or duties defined for the Technical Consultant upon review for 2/11/2020. The findings include: 1. Documentation on 2 /11/2020 of a designated Technical Consultant on the CMS-209 Personnel Report Form without written responsibilities or duties defined. 2. Interviews at approximately 2:00 p.m. on 2/11/2020 with the Laboratory Director and Technical Consultant confirmed there were no written responsibilities or duties defined for the laboratory Technical Consultant upon review on 2/11/2020. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES 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: ========== Based on the lack of 4 of 5 testing

	personnel competency documents containing the 6 CLIA competency criteria for performing Complete Blood Counts (CBC) and upon interview with the Technical Consultant, determined the Technical Consultant failed to ensure complete annual competency evaluations for testing personnel for 2018 and 2019. The findings include: 1. There were no competency evaluations containing the 6 CLIA competency criteria for 4 testing personnel in 2018 and 2019 for performance of CBC testing. 2. Upon interview at approximately 2:00 p.m. on 2/11/2020 with the Technical Consultant, it was confirmed the Technical Consultant failed to document competency assessments to contain the 6 CLIA criteria for 4 of 5 testing persons in 2018 and 2019 for CBC testing. ==========