

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2104504	(X3) Date Survey Completed 05/24/2018
Name of Provider or Supplier Baby Company Cary	Street Address, City, State 226 Ashville Avenue, Suite 20, Cary, NC	
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	<p>A complaint investigation survey was conducted at the facility May 24, 2018. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified June 14, 2018 at approximately 4:55 p.m. The laboratory failed to identify and correct problems in the general laboratory systems. The laboratory failed to establish and follow policies and procedures for evaluating testing personnel competency and failed to enroll in proficiency testing or establish a system to verify the accuracy of its fern and wet prep/KOH (potassium hydroxide) tests at least twice a year. The laboratory director failed to provide overall management and direction for the laboratory. The laboratory director failed to ensure written procedures were established and followed for the performance of laboratory tests. The laboratory director failed to ensure laboratory test reports included all required information. The laboratory director failed to ensure job descriptions indicated the laboratory duties and responsibilities each testing personnel was authorized to perform and failed to ensure testing personnel were trained and the training was documented prior to testing patient specimens. Based on the severity of the deficiencies, the Immediate Jeopardy was not abated and the laboratory was placed on a 23 day revocation track.</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, observation, and staff interview 5/24 /18 the laboratory failed to follow manufacturers' instructions for storage of reagents and supplies to ensure accurate and reliable test performance. Findings: During a tour of the laboratory at approximately 2:20 p.m., surveyors observed the following</p>

supplies stored in the laboratory at room temperature: McKesson Consult Diagnostics 10SG Urine Reagent Strips, Consult hCG Diagnostics Urine Test cartridges, and Alere HemoPoint H2 Microcuvettes. Review of manufacturers' instructions revealed: 1. The McKesson Consult Diagnostics 10SG Urine Reagent Strips product insert states, "...STORAGE AND STABILITY...Store as package in the closed canister or the sealed pouch either at room temperature or refrigerated (2-30 Degrees C or 36-86 Degrees F)....DO NOT FREEZE...". 2. The Consult HCG Diagnostics Urine Test product insert states, "...STORAGE AND STABILITY...Store as packaged in the sealed pouch at 36-86 Degrees F / 2-30 Degrees C...DO NOT FREEZE...". 3. The Alere HemoPoint H2 User Manual states, "... 4.1 Taking a Sample ... Pay attention to the following notes, to preserve the integrity of the Alere HemoPoint H2 Microcuvette: Store the cuvettes only in the original container and at room temperature (59-86 degrees F / 15-30 degrees C). ..." During interview at 5:00 p.m., the Regional Director of Clinical Operations stated that they were not aware that monitoring the storage conditions (room temperature) was required by manufacturer. She verified that the laboratory had not monitored and documented room temperature in the laboratory on a daily basis.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on the absence of records, the deficiencies cited at D5209 and D5217, review of compliance checklists, and interview with staff 5/24/18, the laboratory failed to establish and follow policies and procedures for a comprehensive quality assessment program designed to identify and correct problems in the general laboratory systems and prevent their recurrence. The laboratory did not have a written quality assessment plan available for review at the time of the survey. The laboratory failed to identify and correct problems in the general laboratory systems identified during the survey: 1. The laboratory failed to establish and follow policies and procedures for evaluating testing personnel competency (see D5209). 2. The laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of its fern and wet prep/KOH (potassium hydroxide) tests at least twice a year (see D5217). During interview at approximately 6:20 p.m., the Senior Vice President of Clinical Programs stated that they have clinical compliance checklists that they complete on a routine basis, but they don't include specific laboratory items such as personnel competency and verification of accuracy for fern and wet prep/KOH tests. Review of the "Clinical Compliance Checklist (Monthly)" and the "CABC Compliance Checklist (Biannual)" revealed: 1. The "Clinical Compliance Checklist (Monthly)" stated on page 2-3 "... Clinical Equipment (Visually inspect; check batteries or electrical cords, if applicable; determine if additional maintenance required based on manufacturer specifications. A check indicates all such items are in working order. Leave unchecked and write a note if needing maintenance/repair or this item is not present in your facility.)" The

equipment list included the Microscope, Glucometer, and Hemapoint. 2. "CLIA license" was the only laboratory item on the "CABC Compliance Checklist (Biannual)".

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 personnel records and staff interview 5/24/18, the laboratory failed to establish and follow written policies and procedures for assessing the competency of testing personnel. Review of personnel records for 11 of 11 testing personnel who perform fern and wet prep/KOH (potassium hydroxide) tests revealed there were no competency evaluation records available for review. During the survey at approximately 2:50 p.m., the Regional Director of Clinical Operations provided surveyors with a "Proficiency Testing for CLIA" document (last modified 4/5/18) which stated "The ability to perform microscopy should be assessed following hiring and periodically thereafter. Retraining and reassessment of performance needs to be done when problems are identified with employee performance. A CLIA competency assessment form (below) will be completed on hire and thereafter on an annual basis. ..." The "CLIA Competency Assessment" form stapled to the "Proficiency Testing for CLIA" document included employee instructions to watch a training video, review the procedure, and perform the procedure while being observed. The form also included instructions for the "observer" to directly observe the employee's performance of each step of the procedure and test the employee's problem solving skills with a question or observe the employee resolving a problem. The form included assessment of specimen handling, test performance, quality control, data management, and problem solving, with satisfactory or unsatisfactory performance. Spaces for comments and corrective action were located at the bottom of the form, along with signature and date spaces to be completed by the employee and the "observer". During interview at approximately 4:20 p.m., the Regional Director of Clinical Operations stated that they had not performed any competency evaluations using the new form yet.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on the absence of records and staff interview 5/24/18, the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of the fern and wet prep/KOH (potassium hydroxide) tests at least twice a year. There were no proficiency testing records or accuracy verification records available for review. During interview at approximately 1:00 p.m., the Regional Director of Clinical Operations stated that the laboratory had not enrolled in proficiency testing and she confirmed that the laboratory did not have a system in place to verify the accuracy of the fern and wet prep/KOH tests at least twice a year. She stated that providers work

with a "mentor" during training and they look at fern and wet prep/KOH slides together, but the readings are not documented and it only occurs as a part of training for new testing personnel, not on a regular basis.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on the absence of a written procedure manual and interview with staff 5/24/18, the laboratory failed to establish and follow written procedures for the performance of laboratory testing. The laboratory did not have written, step by step procedures for fern and wet prep/KOH (potassium hydroxide) tests, including: a. instructions for specimen collection; b. the laboratory's system for labeling patient specimens and slides to ensure positive identification and optimum integrity throughout the testing process; c. criteria for specimen acceptability and rejection; d. microscopic examination instructions; e. interpretation of results (elements identified and how they are quantified); f. normal or reference ranges; g. instructions for recording and reporting patient test results in the electronic medical records system. Based on the surveyors' request for policies and procedures, only the following items were provided: CDC Guide for Disinfection and Sterilization in Healthcare Facilities 2008, Pathology Outreach Services Manual from a local pathology laboratory, "Disposal of Trash" policy, "Employee Health Policies", "Infection Control" policy, "Exposure Control Plan", "Latex Allergy" policy. During interview at approximately 2:40 p.m., the Regional Director of Clinical Operations confirmed that the laboratory did not have a laboratory procedure manual which included the required information.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of 4 random patient test reports printed from the electronic medical records system (patients #1, #2, #3, #4) and interview with staff 5/24/18, the laboratory's test reports did not include all required information. Review of patient test reports revealed laboratory test results were documented in the "Progress Note" section in the patients' electronic medical records. Review of the printed test reports revealed: 1. 4 of 4 patient test reports did not include the laboratory's address. 2. 2 of 4 (#1 and #2) did not indicate the test performed. a. The test report for patient #1 stated

	<p>in the Progress Note "... +hyphae (scant), negative clue cells, negative whiff test...". b. The test report for patient #2 stated in the Progress Note: "... Microscopy: No clue cells noted, Negative whiff test, + yeast cells. ...". During interview at approximately 6:10 p.m., the Regional Director of Clinical Operations and the Senior Vice President of Clinical Programs stated they were unaware their test reports did not include all required information.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on random review of 4 patient test reports printed from the electronic medical records system (patients #1, #2, #3, #4) and interview with staff 5/24/18, the laboratory's test reports did not include reference ranges or normal values for the wet prep/KOH tests. Review of patient test reports revealed laboratory test results were documented in the "Progress Note" section in the patients' electronic medical records. Review of the printed test reports revealed that 4 of 4 patient test reports did not indicate reference ranges or normal values. During interview at approximately 6:10 p.m., the Regional Director of Clinical Operations and the Senior Vice President of Clinical Programs stated they were unaware their test reports did not include all required information.</p>
<p>D5980</p>	<p>PPM LABORATORY DIRECTOR CFR(s): 493.1355</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359.</p> <p>This CONDITION is not met as evidenced by: Based on the absence of policies and procedures, review of personnel records, and staff interview 5/24/18, the laboratory director failed to provide overall management and direction for the laboratory Findings: 1. The laboratory director failed to ensure written policies and procedures for assessing the competency of testing personnel were established and followed (see D5209). 2. The laboratory director failed to ensure that the laboratory enrolled in proficiency testing or established a system to verify the accuracy of the fern and wet prep/KOH (potassium hydroxide) tests at least twice a year (see D5217). 3. The laboratory director failed to ensure written procedures were established and followed for the performance of laboratory tests (see D5401). 4. The laboratory director failed to ensure test reports included all required information (see D5805 and D5807). 5. The laboratory director failed to ensure job descriptions included laboratory duties and responsibilities and failed to ensure testing personnel were trained and the training was documented prior to testing patient specimens (see D5983).</p>
<p>D5983</p>	<p>PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of personnel files and staff interview 5/24/18, the laboratory director failed to provide oversight for the laboratory to ensure (1) TP (testing personnel) job descriptions included laboratory duties and responsibilities and (2) all testing personnel were trained and the training was documented prior to performing patient fern and wet prep/KOH (potassium hydroxide) tests. Findings: 1. Review of personnel files revealed the job descriptions did not include laboratory duties and responsibilities. Examples: a. The "Certified Nurse Midwife" job description in TP #2's file stated "a. Description ... The CNM is responsible for the management of the low risk woman and fetus throughout the labor and birth process. The CNM also provides women's primary gynecological health including family planning, well woman visits, assessment and management of noncomplex GYN problems, routine primary health care services, and appropriate screening and health education. ... d. Responsibilities and Duties ... The CNM participates in ongoing quality improvement and professional development activities, including mentorship of new graduates and new hires, assists in recruitment of new clients, facilitates and maintains CABC accreditation standards, and remains current with certification and licensure requirements ..." The job description did not include laboratory duties and responsibilities that the testing personnel was authorized to perform. b. The "CNM Fellow" job description in TP #3's file stated "... CNM Fellows will be placed in existing ... centers, where they will function primarily in the 'Call 2 - LBRP' and 'Clinic 2' roles, as described below. Call 2 - LBRP (Labor, Birth, Recovery, Postpartum): In this role, the CNM Fellow is the answering service contact and has primary triage responsibility for intrapartum care and after-hours/weekend calls. Under the supervision of an experienced CNM mentor, the CNM Fellow provides necessary care, support, and management from admission to the birth center through discharge or transfer. Clinic 2 - Has primary responsibility for postpartum/newborn (home / hospital / TouchCare) and same-day / walk-in encounters, as well as general clinical operations (e.g. reviewing labs, chart reviews) and tasks delegated by Clinic 1. ..." The job description did not include laboratory duties and responsibilities that the testing personnel was authorized to perform. c. The laboratory director's file did not include a job description which indicated the duties and responsibilities the laboratory director is required to perform, including: ensuring testing personnel training and competency, ensuring enrollment in proficiency testing or verification of accuracy for the fern and wet prep/KOH tests, ensuring the availability of a complete and current procedure manual for the laboratory, and ensuring patient laboratory test reports contain all required information. 2. Review of personnel files revealed the laboratory had several different forms that were used to document orientation and training, but none of the forms included training for fern and wet prep/KOH tests. Examples: a. The "CNM Clinical Staff Orientation Checklist" (updated 7/1/17) stated "For training resources, see your personalized clinical training program (Trello) and consult with your mentor or supervisor. Use this form for CNM validation of training. When completed the form is placed in personnel file and serves to acknowledge satisfactory completion of training. CNMs asked to observe readiness must enter initial and date. Use NA if not applicable." The form included a checklist with the training "Topic", a column for the date training was completed for each topic, a "CNM initial" column, and a "CNM check off" column. The "Topic" column contained items such as "Clinical Roles and Scheduling", "Set Up for Labor and Birth", "Medication Safety", and "Administering Nitrous Oxide". The only laboratory topics included were

"Drawing, Ordering and Reviewing Labs" and "Microscopy". There was no additional information to indicate what tests were included under the topic of "Microscopy". b. The "Clinical Staff Orientation Checklist" (updated 4/18/18) stated "For suggested and required training resources, see your personalized clinical training program (Trello) and consult with your mentor or supervisor. This form is accompanied by the attached 'Critical Skills Checklist.' Completion of both forms acknowledges satisfactory completion of your training program, and documented readiness for clinical practice." The only laboratory topic included on the "Clinical Staff Orientation Checklist" was "Ordering and Reviewing Labs". The "Critical Skills Checklist" did not include any laboratory-related items. c. The "... CNM ORIENTATION CHECKLIST" observed in the laboratory director's personnel file stated on page 2 "... 7. EMR ... labs - how to enter labs, make sure to enter date lab was DONE ...". On page 3, it states "... 9. END OF CLINIC DAY TASKS make sure all lab request are filled out and arrangements for courier p/u done. ... Review, sign off, and update encounter with lab/US results and prior records ... Re-stock tables, lab supplies and laundry in table drawers and birth suites ...". On page 4, it states "EQUIPMENT ... 20. HEMOGLOBIN MACHINE Calibration before use Correct method of collection and processing 21. GLUCOSE MACHINE Calibration before use Correct method of collection and processing ...". Items on pages 1, 2, and 3 included initials in the "CNM initials" column to indicate training. There were no initials recorded beside the "HEMOGLOBIN MACHINE" or the "GLUCOSE MACHINE" items on page 4. During interview at approximately 1:00 p.m., the Regional Director of Clinical Operations stated that providers work with a "mentor" during training and they look at fern and wet prep/KOH slides together, but the readings are not documented. During an interview at approximately 5:25 p.m., she confirmed that they did not have training records which specified the laboratory tests each testing personnel was trained to perform.