

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0665601	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Bbh Pcn Gardendale	Street Address, City, State 430 Fieldstown Road, Gardendale, AL	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the Laboratory Directory (LD), who also serves as the Technical Consultant, the surveyor determined the laboratory failed to ensure the testing personnel and LD signed the attestation statement for Hematology, Event #2, 2018. This affected one of six proficiency testing events (2017-2018), reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records for 2017 and 2018 revealed the LD nor the testing personnel signed the attestation statement for the Hematology testing, Event #2, 2018. 2. In an interview on 2/12/2019 at 1:45 PM, the surveyor discussed the above noted findings with the Laboratory Director.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records for 2017 - 2018, and an interview with the Laboratory Director (also serving as the Technical Consultant), the surveyor determined the laboratory failed to implement and document corrective actions for failed proficiency testing results for Events #2 and #3 of 2017. This affected two of six proficiency testing events reviewed by the</p>

surveyor. This is a repeat deficiency. The findings include: 1. A review of the proficiency testing records for 2017 and 2018 revealed the laboratory performed testing for vaginal wet preparations and urine sediment examinations (moderate-complexity, non-regulated CLIA analytes). These tests have since been discontinued from the laboratory's test menu. 2. The laboratory scored zero percent (0 %) for the vaginal wet preparation for Event #2, 2017 and fifty percent (50 %) for the urine sediment examination for Event #3, 2017. The testing personnel documented the laboratory should not have reported the vaginal wet preparation, because the testing had been discontinued (see the interview in paragraph 4. The test was not discontinued until after the first testing event of 2018). 3. The laboratory failed to implement and document corrective actions for the above mentioned failed proficiency testing scores. 4. In an interview on 2/12/19 at 1:40 PM, the surveyor inquired of the Laboratory Director (also the Technical Consultant) the actual date vaginal wet preparations and urine sediment examinations had been discontinued. The Laboratory Director (LD) stated the testing was discontinued after the first event of 2018, because the physicians no longer wanted to interpret the slide tests. The surveyor discussed with the LD the incorrect statement made by the testing personnel in the proficiency testing records, regarding the discontinuance of the testing in 2017 and the failure to implement and document corrective actions for the failed results.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the Abbott Cell Dyn Emerald operators' guide, a review of the calibration and daily quality control records (including the data logs), and an interview with the Laboratory Director (also serves as the Technical Consultant) and the testing personnel, the surveyor determined the laboratory failed to follow the manufacturer's guidelines to verify four of six calibrations, reviewed by the surveyor for the review period, 2/08/17 - 2/12/19. This is a repeat deficiency. The findings include: 1. A review of the calibration records for the Emerald reveal the following calibrations: a) 5/10/17 at 3:42 PM. The staff documented no quality control (QC), none in stock. b) 12/07/17 at 5:31 PM. Only AM QC was done. c) 7/12/18 at 3:29 PM. QC was documented for the PM, following the calibration. d) 7/17/18 at 2:04 PM. Only AM QC was done. e) 11/15/18 (manual calibration by the manufacturer). f) 1/30/19 at 3:35 PM. 2. The quality control records failed to indicate QC was performed after four of the six calibrations, listed in paragraph 1. 3. A review of the calibration procedure in the Emerald operators' manual revealed the following instructions: "...Verify calibration as directed in the Calibration Verification Procedure..." (using the calibrator). Laboratories also have the option of running QC to verify their calibration. 4. Prior to the exit summation at 1:45 PM on 2/12/19, the

surveyor discussed the findings with the laboratory director and testing personnel (TP) #1. The surveyor provided the testing personnel an opportunity to locate and provide the quality control she said she ran after the calibrations. The testing personnel returned and said she was not able to locate documentation the quality control was run after the calibrations. The Laboratory Director stated she explained to the testing personnel this would be a citation.

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 a review of the personnel records and an interview with the Laboratory Director (also the Technical Consultant), the surveyor determined the laboratory director failed to ensure Testing Personnel (TP) #2 presented the appropriate educational credentials, prior to performing laboratory testing. This affected one of three testing personnel, who perform moderate complexity testing. The findings include: 1. The laboratory listed TP #2 on the CMS form #209, Laboratory Personnel Report, as laboratory testing personnel. 2. A review of the personnel records revealed a certification record on file for TP #1, but no high school diploma or degree, which would meet the CLIA requirements for laboratory testing personnel. 3. In an interview on 2/12/2019 at 1:45 PM, the surveyor discussed the findings and qualifications with the Laboratory Director (LD). After reviewing the personnel file, the LD stated she would fax the document to the State Agency. At 12 Noon on 2/22/2019, this document had not been received by the State Agency (CLIA).