

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1004954	(X3) Date Survey Completed 01/18/2022
Name of Provider or Supplier Bhs Physicians Network	Street Address, City, State 1626 E Common Street, New Braunfels, TX	
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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1421 D6063 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing a competency assessment for 1 of 1 technical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 01/18/2022) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment of the technical consultant. 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 01/18/2022 at 9:45 a.m. in the</p>

break room revealed the laboratory did not assess the competency of the technical consultant. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/19/2019

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of the Alere Triage quality control records, and staff interview, it was revealed the laboratory failed to verify the criteria for acceptability of all control materials. Findings include: 1. A review of the laboratory's policy titled 'Quality Control' stated the following: "Each level of the new control material must be evaluated prior to use to verify that control results fall within manufacturer stated 2SD ranges. Results may be compared against those found within the package insert and filed in the quality control binder, or documented on the chart template, to show acceptability of new lot control material." 2. A random review of the Alere Triage Total 5 Control quality control reports from 2021 revealed the following quality control lot numbers were placed into service and the laboratory failed to verify the new quality control lot: Lot # 3659 Lot # 3671 Lot # 3661 Lot # 3673 Lot # 3774 Lot # 3796 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 01/18/2022) on 01/18/2022 at 10:00 a.m. in the break room revealed the laboratory failed to have documentation of new quality control lots being verified. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/19/2019

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education to determine the

qualifications of 1 of 13 testing personnel to perform moderately complex testing (refer to D6065). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/19/2019

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 13 testing personnel. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 01/18/2022) revealed the laboratory identified 13 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education which would qualify the testing personnel to perform moderate complexity testing for: Testing person #5 3. The laboratory was asked to provide documentation of education for the identified testing personnel. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 01/18/2022 at 09:45 a.m. in the break room, after review of the records, confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/19/2019