

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0055097	(X3) Date Survey Completed 10/06/2021
Name of Provider or Supplier Bsa Physicians Group,Inc Db a Bsa Urgent Care Cente	Street Address, City, State 4510 S Bell St, Amarillo, 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
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: Review of manufacturer's instructions, patient final reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Sofia SARS Antigen and the Sofia Flu+SARS Antigen test kits for testing 16348 patients tested between August 1, 2020 and October 6, 2021. The findings included: 1. Review of the manufacturer's instructions found on page 19 under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the Sofia SARS Antigen FIA and the Flu+SARS Antigen FIA must include with the test result reports, all authorized Fact Sheets." 2. Review of patient results found no fact sheets included with the final report for three of three patient reports reviewed. 3. Interview of the Technical Consultant conducted September 21, 2021 at 10:32 AM confirmed that the Fact Sheets were not included with the patient test results for SARS COV-2 testing.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the College of American Pathologists (CAP) proficiency testing records from 2020 and 2021, policies and procedures and staff interview, the laboratory failed to review and evaluate proficiency testing results for one of five events for hematology , and one of three events for clinical Microscopy . The findings included: 1. Review of CAP proficiency testing records from 2020 and 2021 (3 testing events annually) found no documentation of review for: the FH2-B 2021 Hematology Auto Differentials testing event. the CM-A 2021 Clinical Microscopy Event. 2. Review of the laboratory's written procedure titled External Proficiency Testing found on page two "I. The review form and Survey together with any documentation is rerouted to the Medical Director for final Review and filing." 3. Interview of the Technical Consultant conducted on September 21, 2021 at 2:25 PM confirmed that proficiency testing records for these events was not documented.

D5461

CONTROL PROCEDURES

CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's policy, reagent IFUs from manufacturer, the laboratory's records from 2018-2021, and confirmed in an interview, the laboratory failed to document quality control testing after change in reagents on the Beckman Coulter AcT Diff 2 hematology analyzer for CBC testing. The findings were: 1. Review of the policy titled "CBC AcT Diff 2 (Effective date: 4/14/2009; Review /Revised: 9/28/2015)" revealed the laboratory having three reagents for the Beckman Coulter AcT Diff 2 hematology analyzer (SN#AT44535) for CBC testing. diff AcT Pak reagent diff AcT Tainer reagent AcT Rinse Shutdown Diluent 2. Review of Coulter diff AcT Pak reagent kit (Ref: 8547134; 772249-AE) IFU revealed under Storage, Stability, and Disposal, "If the operating environment of your laboratory is 16-25C, discard opened container after 60 days. If the operating environment of your laboratory is 26-35C, discard opened container after 30 days." 3. Review of Coulter diff AcT Tainer reagent kit (Ref: 8547135; 772247-AF) IFU revealed under Storage, Stability, and Disposal, "Opened containers are stable for 30 days when used at 16-25C." 4. Review of Coulter AcT Rinse Shutdown Diluent (Ref: 8547113; 772252-AF) IFU revealed under Storage, Stability, and Disposal, "Open containers are stable for 30 days when used at 16-35C." 5. Review of the laboratory records from 2018-2021 revealed no documentation of reagent changes on the Beckman Coulter AcT Diff 2 hematology analyzer for CBC testing. 6. Review of the CMS 116 signed by the LD on 9/20/21 revealed the CBC testing annual volume for hematology was 5952. 7. An interview with the technical consultant on 9/21/21 at 12:11 PM in the Lab confirmed quality control testing was not performed after change of reagents on the Beckman Coulter AcT Diff 2 hematology analyzer. Key: IFU=Instruction for use CBC=Complete Blood Count LD=Laboratory Director

D6061

CLINICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1419(c)

The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy, and confirmed in an interview the Clinical consultant failed to ensure the reference range necessary for interpretations was included in patient final reports for one of 16 analytes (RDW) for CBC testing. The findings were: 1. Review of the CBC AcT Diff 2 Policy (Effective date: 4/14/2009, Reviewed/Revised: 9/25/2015) revealed the reference range for RDW was, Male Results 11.5%-14.5% Female Results 11.5%-14.5% Child Results 12.7%-15.0% 2. One example of patient final reports reviewed revealed no reference range included for interpretation for RDW result. 9/16/21 Patient ID: 945265 3. An interview with the technical consultant on 9/21/21 at 12:18 PM in the office confirmed the RDW reference range was not included on the patient final reports. Key: CBC=Complete Blood Count RDW=Red cell distribution width