

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1004466	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier G Scot Johnson Md Pa	Street Address, City, State 5110 North 10th Street Suite E, Mcallen, 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	<p>The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was 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.</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 surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for test performance on the Stanbio QuStick Strep A Rapid Test Strip (Procedure No. 6000). The findings were: 1. Surveyor observation on November 28, 2018 10: 05 a.m. in the laboratory revealed the testing person performing two rapid strep patient tests. Once the timer went off after one minute, she did not removed the patient swab. 2. The manufacturer's instructions (DN: 1155972104) under, "Test Procedure" stated, "3. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the</p>

tube. Discard the used swab." 3. The following two patients were tested and results available on the patients' charts when the manufacturer's instructions were not followed: Visit # 1328777 Date: 11/29/2018 Result: Negative Visit # 132876 Date: 11/29/18 Result: Negative 4. An interview with the technical consultant on 11/29/2018 at 10:50 hours in the office confirmed the findings.

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 submitted Form CMS 209, 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 5 testing personnel to perform moderate complexity testing (refer to D6065). Key: CMS - Centers for Medicare and Medicaid Services

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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 5 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 11/26/2018) revealed the laboratory identified 5 testing personnel. 2. A review of the laboratory's personnel records revealed 1 of 5 testing personnel did not have documentation of education to qualify them to perform moderate complexity testing. Testing personnel #1 had a start date of 05/28/2018 and a termination date of 10/31/2018. 3. Review of the personnel records for testing personnel five (as listed on Form CMS 209) revealed the records available for review was a medical assistant certificate. 4. An interview with the technical consultant on 11.29/2018 at 09:40 hours in the office confirmed the laboratory did not have documentation of education for testing personnel #5. Key: CMS - Centers for Medicare and Medicaid Services