Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0995218	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
G Athanasi Orfanos Md Pediatrics	2703 W Trenton, Edinburg, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on surveyor direct observation, review of manufactuer's instructions, review of patient records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions for ensuring patient test strips were closed for the Consult Strep A Test. The findings included: 1. Surveyor observation on December 16, 2021 at 12:50 hours in the laboratory found 1 vial of Consult Strep A patient test strips left open. There were two remaining test strips in the container. 2. Review of the maufactuer's instrucitons for the Consult Strep A (11559955905) under "Storage and Stability" it stated, "...The test dipstick must remin in the closed canister until use." 3. An interview with testing personnel 1 (as listed on Form CMS 209) on

	December 16, 2021 in the laboratory confirmed the findings. She agreed the test strips were not closed. Key: CMS - Centers for Medicare and Medicaid Services
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation by surveyor, review of laboratory policies, and confirmed in interview of laboratory personnel, the laboratory failed to follow its policy for specimen labeling for 1 of 1 specimens observed in the laboratory. The findings included: 1. Surveyor observation made on December 16, 2021 at 12:46 hours in the laboratory found 1 unlabeled pediatric purple top on top of the Medonic hematology analyzer. 2. Review of the laboratory's policy titled "Specimen Identification" approved by the laboratory director on January 4, 2011, it stated, "Each specimen must have unique identifiers such as patient name, birth date, social security number or other identifying number. The identifiers should be used throughout the testing process, so that results can be confidently used in patient care. This can be done by placing an identification label on each specimen when it is collected and by labeling all related materials (test tubes, slides, etc.) with the same identification information. 3. The laboratory was asked to provide documentation of following its specimen labeling policy for 1 of 1 patient specimen found unlabeled in the laboratory during the initial tour of the facility. No documentation was provided. 4. An interview with testing personnel 1 (as listed on Form CMS 209) on December 16, 2021 at 12:46 hours in the laboratory confirmed the findings. When asked why it could not be determined who the specimen belonged to, she stated, "Because it does not have a name or date of birth on it."
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions, review of patient test records, and staff interview, the laboratory failed to ensure 4 of 10 CBC (complete blood count) results with flags were resolved prior to their release to the provider. The findings included: 1. This is a repeat deficiency from the survey dated January 31, 2020. 2. A review of the manufacturer's instructions for the Medonic hematology analyzer (SN 26075 Article no: 1504283 November 2012) under the section titled "9.2 System Messages" under "Abnormalities" stated "Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cell., which may cause aberration in the automated analysis ...." BD - WBC Diff: High interference between population Action: blood sample too old or pathological sample. follow laboratory's protocol for verification of results. OM - WBC Diff: Only once WBC population found; slide review advised Action: blood sample too old or pathological sample. follow laboratory's protocol for verification of results." 3. Review of random patient test records from October 2021 revealed the following 4 of 10 patient results with flags did not have verification of flags prior to their release to the healthcare provider. Seq # Date 4925 10-02-2021 Flag BD 4935 10-03-2021 Flag OM 5229 10-25-2021 Flag AF 5231 10-25-2021 Flag BD 4. A review of CMS 116 signed by the laboratory director December 16, 2021 found the laboratory performed 28,188 CBC tests annually. 5. An interview with testing personnel #1 (as listed on form CMS 209) December 16, 2021 at 13:30 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services Seq - Sequence
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview of laboratory personnel, the technical consultant failed to identify that testing personnel needed training or a regular inservice regarding resulting of flags on CBCs (complete blood count). (Refer to D5403)