

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0995218	(X3) Date Survey Completed 10/07/2025
Name of Provider or Supplier G Athanasi Orfanos Md Pediatrics	Street Address, City, State 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 and 2025, and staff interview, the laboratory failed to ensure proficiency testing samples were tested the same number of times as patient samples. The findings included: 1. A review of the laboratory's policy titled "Critical Values/Repeat Criteria Policy" (approved 06/12 /2015) determined complete blood count results were to be repeated when they fell outside the following criteria: White Blood Cell less than 2.0 and greater than 25.0 Hemoglobin less than 7.5 and greater than 18 Hematocrit less than 25 and greater than 55 Platelet less than 50 or greater than 800 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 (events 1, 2 and 3) and 2025 (events 1 and 2) identified the following proficiency testing results which met the facility's criteria for repeat testing, however the laboratory failed to have documentation of repeat testing: a) 2024 Event 1 Sample: HSY-02 Tests: Hemoglobin 5.9 Hematocrit 17.2 Sample: HSY-03 Tests: Hemoglobin 19.1 Hematocrit 61.2 b) 2024 Event 3 Sample: HSY-14 Tests: Hemoglobin 5.8 Hematocrit 15.6 c) 2025 Event 2 Sample: HSY-09 Tests: Hemoglobin 5.8 Hematocrit 16.3 3. The technical consultant confirmed the findings in an interview conducted on 10/07/2025 at 0945 hours in the office.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by</p>

the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of patient test records from September 2025, and staff interview, the laboratory failed to following its policy for ensuring flagged Complete Blood Count (CBC) results were not reported to the provider for 2 of 3 results. The findings included: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC's" (approved 02/17/2022) determined: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluated flagged differential according to procedures in the unit's operator's manual. Lab staff must ensure sample requirements are met, that the unit is in good condition order, and that the testing procedure is correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature for 15 to 20 minutes, or by recollecting the sample. If the flags disappear, then report that result. If the flags persist, then the laboratory will confirm the abnormal differential by sending out to a reference laboratory or crossing out the flagged values. Crossing out of the flagged parameters has to occur prior to handing the results to the provider. These results cannot be used to diagnose the condition of the patient. Flagged results will not be reported at any time." 2. A sampling of patient results from September 2025 identified the following 2 of 3 flagged CBC results which were reported to the provider: a) Account number: 33024 Date: 09/12/2024 Flagged Results: Neutrophil percent Lymph percent Monocytes percent b) Account number: 5631 Date: 09/29/2025 Flagged Results: Neutrophil percent Lymph percent Monocytes percent Neutrophil count Lymph count Monocytes count 3. The technical consultant confirmed the findings in an interview conducted on 10/07/2025 at 1100 hours in the laboratory.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (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 laboratory's quality control records from August 2025 and September 2025, review of patient test records, and staff interview, the laboratory failed to ensure quality control results for Complete Blood Count were acceptable prior to reporting patient results. The findings included: 1. A review of the laboratory's policy titled "CONTROL POLICY" (approved 1/4/11) found: "Control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All control results and remedial actions must be recorded and records kept for at least two (2) years. Patient testing must not be performed or reported when control test results are outside the expected range." 2. A review of the laboratory's Complete Blood Count quality control results from August 2025 and September 2025 identified two days when the laboratory reported patient results without at least two levels of acceptable quality control results. They were: a) Date: 08/31/2025 Level 1: not tested Level 2: quality control failed (flagged results) Level 3: acceptable b) Date: 09/07/2025 Level 1: acceptable Level 2:

quality control failed (flagged results) Level 3: quality control failed (flagged results) 3. A review of patient results from August 31, 2025 and September 9, 2025 identified the following patients who's results were reported without acceptable quality control: a) August 31, 2025 Account no.: 30979 b) September 7, 2025 Account no.: 14419 Account no.: 35559 Account no.: 26093 4. The technical consultant confirmed the findings in an interview conducted on 10/07/2025 at 1100 hours in the office.

D5813

TEST REPORT
CFR(s): 493.1291(g)

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, review of the laboratory's patient test results from August 2025 and September 2025, review of the laboratory Panic/Critical Value log and staff interview, the laboratory failed to have documentation of the notification of 2 of 2 critical values. The findings included: 1. A review of the laboratory's policy titled "Critical Values/Repeat Criteria Policy" (approved 06/12/2015) determined the laboratory defined the following Critical Values: a) White Blood Cell less than 2.0 and greater than 25.0 b) Hemoglobin less than 7.5 and greater than 18.0 c) Hematocrit less than 25 and greater than 55 d) Platelet less than 50 or greater than 800 2. A review of the laboratory policy titled "Reporting Critical Values" (approved 01/04/2011) determined: "It is the policy of this laboratory to document the reporting of Critical Values. Document: 1. Who was notified 2. When was the person notified 3. By whom was the person notified" 3. A review of the patient results from August 2025 and September 2025 identified the follow 2 patient results which met the laboratory's critical value criteria: a) Date: 08/11/2025 Account no.: 31992 Hemoglobin: 7.1 Hematocrit: 19.1 b) Date: 09/29/2025 Account no.: 11425 Hemoglobin: 18.1 4. A review of the laboratory's Critical Value Log determined the two critical values were not documented on the log as required by the facility. 5. An interview with the technical consultant on 10/07/2025 at 1100 hour in the laboratory confirmed the findings. a) Date: