

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0258592	(X3) Date Survey Completed 09/12/2019
Name of Provider or Supplier Internal Medicine Specialists Of Atlanta, Pc	Street Address, City, State 1800 Howell Mill Road, Suite 175, Atlanta, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on September 12, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the laboratory technical supervisor , the laboratory testing personnel and lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of Hematology PT 2019 events #1 & #2 revealed no attestation statements available for review. 2. Review of Serology PT 2019 events #1 & #2 revealed attestation statements were not signed by the LD. 3. Interview with the technical supervisor (CMS 209 form) on 9/12/19 at approximately 2:50 PM in the breakroom, confirmed the aforementioned attestation discrepancies.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed</p>

by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of proficiency test (PT) records and interview with the laboratory technical supervisor, the laboratory failed to retain original analyzer printouts for hematology. Findings include: 1. Review of Hematology PT 2019 event #1 revealed no original analyzer printouts were available for review. 2. Interview with the technical supervisor (CMS 209 form) on 9/12/19 at approximately 2:50 PM in the breakroom, confirmed the original analyzer printouts were not available for review.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by 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 procedure manual (SOP) review and staff interview, the laboratory failed to include procedures for all testing performed.. Findings: 1. Review of the SOP revealed the lack of written procedures for Complete Blood Counts (CBC), manual differential, urine microscopic exam, Rapid Plasma Reagin (RPR), Proficiency Testing (PT), Corrective Actions, Specimen Rejection, and Duties and Responsibilities for each high complexity required position. 2. Interview with staff #2 (CMS form 209) on September 12, 2019 at 2:53 PM in the breakroom, confirmed the aforementioned procedures were not included in the SOP.

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 procedure manual (SOP) review and staff interview, the laboratory failed to include all criteria required to cover the full scope of testing. Findings: 1. Review of the Complete Blood Cell Count (CBC) procedure, the urinalysis (UA) procedure, and the rapid plasma reagin (RPR) procedures did not cover the full scope of testing. Procedures failed to include criteria definition for manual differential, urine microscopic exam and/or reflex testing for culture and sensitivity, or RPR reflex titer testing. Procedures also lacked criteria for Quality Control, Proficiency Testing, Calibrations, Calibration Verification, Reference Ranges, and Normal Ranges. 2. Interview with staff #2(CMS form 209) on September 12, 2019 at 2:53 PM in the breakroom, confirmed the aforementioned procedures did not cover the full scope of testing.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on urine microscopic slides. Findings include: 1. No QC documents were available to review on urine microscopic slides at the time of survey. 2. An interview with the technical supervisor on 9/12/19 at 2:40 PM in the breakroom confirmed controls were not performed on urine microscopic slides .

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records, environmental charts, and staff interview, the lab failed to document corrective actions when QC or environmental parameters exceeded acceptable limits. Findings include: 1. Review of 2018-2019 Hematology QC records revealed when one (1) or more analytes were out of range, corrective actions were not documented. 2. Review of the 2019 room humidity (RH)

chart revealed the RH was out of range 7 of 21 days in January; 2 of 19 days in February; 10 of 20 days in March; and 1 of 20 days in April. Corrective actions were not documented. 3. Interview with the technical supervisor (CMS 209 form) on 9/12 /19 at 2:50 PM in the breakroom, confirmed the corrective actions were not documented.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on lab report reviews and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Based on review of patient reports #21209, 3357, and 21521 revealed the testing site for in-house lab tests did not contain the name and address of the laboratory location where the test was performed. The syphilis serology reports also did not include the normal/reference range. The urinalysis report also did not include the normal /reference range or units of measurement. 2. Interview with the technical supervisor (CMS 209 form) on 09/12/19 at approximately 2:50 PM in the breakroom, confirmed the corrective actions were not documented.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on American Proficiency Institute (API) proficiency testing (PT) document review and staff interview, the laboratory director (LD) did not ensure corrective actions were documented when any proficiency testing result is found to be unacceptable or unsatisfactory. Findings include: 1. Review of the PT documents revealed corrective actions were not documented for hematology 2018 event #2 MCV score of 40% ; 2017 event #3 and 2018 events #1 & 2 urine creatinine score of 0% (failure to participate). 2. Interview with the technical supervisor (CMS 209 form) on 9 /12/19 at 2:50 PM in the breakroom, confirmed the corrective actions were not documented.