

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0686437	(X3) Date Survey Completed 07/14/2022
Name of Provider or Supplier Family Practice Associates	Street Address, City, State 1776 Old Spring House Lane, 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 Provider Performed Microscopy (PPM) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on July 14, 2022. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the laboratory tour and staff interview, the laboratory failed to implement and establish proper safety procedures to ensure protection from physical, biochemical and biohazardous materials in the laboratory area. Findings include: 1. During the laboratory tour it was observed that there was no flush eyewash equipment (for emergency use) in the laboratory testing and processing area. 2. An interview with both laboratory coordinators during the laboratory tour on 07/14/2022, at approximately 10:30 A.M confirmed the absence of an eyewash flush equipment.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on Quality Control (QC) and Quality Assessment (QA) documents review and staff interview, the laboratory failed to review laboratory QC logs and document quality assessment (QA) activities as required. The Findings include: 1. Laboratory QC documents review revealed the lab director or Technical Consultant (TC) did not review Urinalysis and urine sediments QC logs on a monthly or quarterly basis from 2020 to 2022. 2. Laboratory maintenance logs including; Microscope, Room Temperature, refrigerator, centrifuge logs were not reviewed on a monthly basis or a (QA) checklist to correct problems arising in the lab during testing. 3. An interview with the Laboratory coordinators on 07/14/2022 at 12:15 PM in the break room confirmed the lack of adequate QA checklist and maintenance review in 2020 to 2022.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Quality Assurance(QA) documents review and staff interview, the Lab Director(LD) failed to ensure that proper QA guidelines were followed including regular review of instrument Quality Control (QC) and (QA) data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. (QC) and (QA) documents review revealed the laboratory director did not review maintenance or (QC) logs to identify and correct problems in the laboratory as they occur in 2020 thru date of survey 07/14 /2022. 2. An interview with the laboratory coordinators in the break room on 07/14 /2022, at approximately 12:15 PM, confirmed the LD did not review the aformentioned (QC) and (QA) data in 2020 thru the date of survey 07/14/2022.