

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0906636	(X3) Date Survey Completed 05/23/2019
Name of Provider or Supplier Family Practice Assocs Of Clarksville	Street Address, City, State 23 Professional Park Drive, Clarksville, AR	
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
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: Through a review of the proficiency test attestation records for 2018 and 2019, and interview with laboratory staff, it was determined the testing personnel failed to attest to the routine integration of proficiency test samples in the patient workload for four of four surveys reviewed. Survey findings follow: A) The attestation forms for the following proficiency test events were not signed by the testing personnel: AAFP-2018 Event A, AAFP-2018 Event B, AAFP-2018 Event C and AAFP-2019 Event A. B) In an interview, at approximately 11:10 on 5/22/19, the laboratory director (as listed on the form CMS-209) stated that testing personnel had not signed the attestation forms identified above and the laboratory director had printed the names of the testing personnel on the attestation forms.</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 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</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Through a review of proficiency test documentation for 2018 and 2019, lack of documentation, and interview with laboratory staff, it was determined the laboratory failed to maintain copies of proficiency test instrument print-outs for four of four proficiency test events surveyed. Survey findings follow: A) Review of proficiency testing documentation for AAFP-2018 Event A, AAFP-2018 Event B, AAFP-2018 Event C, and AAFP-2019 Event A revealed that original instrument result print-outs were not included in the documentastion. B) Upon request, the laboratory was unable to produce the instrument print-outs for the events identified above. C) In an interview on 5/22/19 at approximately 11:10 AM, the laboratory director identified on the CMS 209 form confirmed that the instrument print-outs for the events identified above were not available.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Through observations made during a tour of the laboratory and interview it was determined the laboratory had reagent available for use when it had exceeded the expiration date. Survey findings follow: A) During a tour of the laboratory at approximately 10:45 AM on 5/23/19, one of two bottles of HCG Tri-Level Control (Lot # 170371 expiration date 2019-01-31) was observed available for use on the counter where qualitative testing is performed. B) In an interview on 5/23/19 at approximately 10:45 AM, the laboratoery director, identified as number one on the CMS 209 form, confirmed that the HCG control identified above had exceeded its date of expiration and was available for use.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through review of the laboratory's "Quality Control Policy", quality control summary reports, lack of documentation, "Result Listing" report for 10/17/18, and interview it was determined that the laboratory failed to perform quality controls for quantitative

chemistry testing on one of twenty-three days of testing in October 2018. Survey findings follow: A) Review of the laboratory's "Quality Control Policy" revealed that "controls will be run each day of testing before patient results are reported". B) Review of October 2018 quality control summary reports for the Integra 400 chemistry analyzer revealed that no quality control results were listed for October 17, 2018. C) Upon request, the laboratory was unable to produce quality control results for the Integra chemistry analyzer for October 17, 2018. D) Review of the "result listing" report revealed that chemistry testing performed on the Integra 400 chemistry analyzer was reported on fourteen patients, identified as numbers one through fourteen on a separate patient identification list. E) In an interview on May 22, 2019 at approximately 02:55 PM, the laboratory director, identified on the CMS 209 form, confirmed that Integra 400 chemistry quality control was not performed on October 17, 2018 and patient results were reported.