

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2135860	(X3) Date Survey Completed 10/01/2020
Name of Provider or Supplier Walpole Medical Center, Pc	Street Address, City, State 841 Main Street, Walpole, MA	
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 CLIA recertification survey was conducted for the Walpole Medical Center PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) record review and interview with the Technical Consultant (TC), the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar years 2018, 2019, and 2020 (5 total testing events) on 10/1/2020. The review revealed that attestation statements provided by the PT program were not signed by the testing person or laboratory director for Event 1 in 2019 and Event 1 in 2020. The TC confirmed in an interview on 10/1/2020 at 10:45 AM that not all attestation statements were signed by the analyst and the laboratory director. .</p>
D3037	RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on record review and confirmed through interview with the Technical Consultant (TC), the laboratory failed to retain all proficiency testing (PT) records for at least 2 years as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar years 2018, 2019, and 2020 (5 total testing events) on 10/1/2020. The review revealed that the laboratory failed to maintain raw data of the PT results from Event 1 in 2019. The technical consultant and testing person confirmed that the laboratory failed to retain all PT records for at least 2 years on 1/10/2020 at 10:45 AM. .

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on record review and interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer of a new test system before reporting patient test results as evidenced by the following: The laboratory implemented the Medica EasyRA analyzer for Toxicology testing on 11/22/2019. The surveyor reviewed validation studies for the new analyzer on 10/1/2020. The review revealed that the laboratory did not perform accuracy studies with their validation of the new analyzer prior to patient testing. The technical consultant confirmed through interview on 10/1/2020 at 9:35 AM that the laboratory failed to perform accuracy studies prior to reporting patient test results on the new Medica EasyRA analyzer. The laboratory performs 13,000 Toxicology tests annually.