

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2144340	(X3) Date Survey Completed 06/11/2020
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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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT records and the verified with the College of American Pathologists (CAP) PT program, the laboratory failed to have the PT test results released to New York State Department of Health (NYSDOH), Physician Office Laboratory Evaluation Program (POLEP) in the calendar year 2020.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy</p>

to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:
Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes Chloride (CL), BUN, Human Chorionic Gonadotropin (Hcg), Triiodothyronine (T3), Cell Identification (Cell I.D.) and the sub-specialty Endocrinology. The following scores were assigned: Chloride (CL) 2019 third event = 40% 2020 first event = 0% [non-participation] BUN 2019 second event = 60% 2019 third event = 80% 2020 first event = 0% [non-participation] Human Chorionic Gonadotropin (Hcg) 2019 third event = 40% 2020 first event = 0% [non-participation] Triiodothyronine (T3), 2019 third event = 60% 2020 first event = 0% non-participation] Cell Identification (Cell I.D.) 2019 third event = 60% 2020 first event = 0% [non-participation] Sub-specialty Endocrinology 2019 third event = 76% 2020 first event = 0% [non-participation] This is considered unsuccessful PT performance. Refer to D2096, D2107 and D2130.

D2089

ROUTINE CHEMISTRY
CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the speciality Chemistry and the eighteen test analytes. 2020 first event = 0% [non-participation] This is considered unsatisfactory PT performance

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte Chloride (CL) and BUN The following scores were assigned: Chloride 2019 third

event = 40% 2020 first event = 0% [non-participation] BUN 2019 second event = 60% 2019 third event = 80% 2020 first event = 0% [non-participation] This is considered unsuccessful PT performance.

D2100

ENDOCRINOLOGY
CFR(s): 493.843(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes Free Thyroxine (FTY), T3 uptake and Thyroid Stimulating Hormone (TSH) 2020 first event = 0% [non-participation] This is considered unsatisfactory PT performance.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the sub-specialty Endocrinology and the test analytes Triiodothyronine (T3) and Hcg. The following scores were assigned: Sub-specialty Endocrinology 2019 third event = 76% 2020 first event = 0% [non-participation] Triiodothyronine (T3) 2019 third event = 60% 2020 first event = 0% [non-participation] Hcg 2019 third event = 40% 2020 first event = 0% [non-participation] This is considered unsuccessful PT performance.

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

	<p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the speciality Hematology and the test analytes Red Blood Cell Count (RBC), White Blood Cell Count (WBC), Hematocrit (Hct), Hemoglobin (Hgb) and Platelets. 2020 first event = 0% [non-participation] This is considered unsatisfactory PT performance.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes Cell Identification (Cell I.D.) The following scores were assigned 2019 third event = 60% 2020 first event = 0% [non-participation] This is considered unsuccessful PT performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on PT desk review of the PT CMS data reports, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the test analytes Chloride (CL), BUN, Hcg, T3, Cell Identification (Cell I.D.) and the sub-specialty Endocrinology and the test analytes, FTY, T3 uptake, TSH, speciality Chemistry and eighteen test analytes, speciality Hematology and the test analytes WBC, RBC, Hct, Hgb and Platelet. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the PT CMS data reports, the laboratory director failed to</p>

fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the test analytes Chloride (CL), Human Chorionic Gonadotropin (Hcg), Triiodothyronine (T3), Cell Identification (Cell I.D.) and the specialty Endocrinology, FTY, T3 uptake, TSH, speciality Chemistry and twenty two test analytes, speciality Hematology and the test analytes WBC, RBC, Hct, Hgb and Platelet. The following scores were assigned: Chloride (CL) 2019 third event = 40% 2020 first event = 0% [non-participation] BUN 2019 second event = 60% 2019 third event = 80% 2020 first event = 0% [non-participation] Hcg 2019 third event = 40% 2020 first event = 0% [non-participation] Triiodothyronine (T3), 2019 third event = 60% 2020 first event = 0% [non-participation] Cell Identification (Cell I.D.) 2019 third event = 60% 2020 first event = 0% [non-participation] Sub-specialty Endocrinology 2019 third event = 76% 2020 first event = 0% [non-participation] This is considered unsuccessful PT performance. Speciality Chemistry and the twenty test analytes. (FTY), T3 uptake and TSH RBC, WBC, Hct, Hgb and Platelets. 2020 first event = 0% [non-participation] This is considered unsatisfactory PT performance.