

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2079846	(X3) Date Survey Completed 06/06/2022
Name of Provider or Supplier Khoury Medical Care Pc	Street Address, City, State 1184 Brighton Beach Avenue, Brooklyn, NY	
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 verified by 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's Office Evaluation Program (POLEP) in the calendar year 2020, 2021 and 2022. THIS IS A REPEATED DEFICIENCY FROM THE PROFICIENCY TESTING DESK REVIEW CONDUCTED ON MAY 2, 2019.</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</p>

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 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 and PT records from the College of American Pathologists (CAP) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the specialities Endocrinology and Toxicology and the test analyte's Immunoglobulin E Antibody (IgE), Amylase, Chloride (CL), Thyroid Function Test T3 Uptake, Triiodothyronine (T3), Thyroxine (T4) and Lithium The following scores were assigned: IgE, Amylase, T3 Uptake, T3, T4, Lithium and the speciality Toxicology 2021 third event = 0% (failure to participate) 2022 first event = 0% (failure to participate) Speciality Endocrinology 2021 third event = 57% 2022 first event = 51% Chloride 2021 third event = 60% 2022 first event = 40% This is considered unsuccessful PT performance. Refer to D2085, D2097, D2107, D2108, D2118 and D2119

D2075

GENERAL IMMUNOLOGY
CFR(s): 493.837(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte Alpha Fetoprotein (AFP) The following scores were assigned: 2021 third event = 0% This is considered unsatisfactory PT performance

D2076

GENERAL IMMUNOLOGY
CFR(s): 493.837(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the speciality General Immunology. The following scores were assigned: 2021 third event = 56% This is considered unsatisfactory PT performance

D2085

GENERAL IMMUNOLOGY
CFR(s): 493.837(g)

	<p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing 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 and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte IgE. The following scores were assigned: 2021 third event = 0% (failure to participate) 2022 first event = 0% (failure to participate) This is considered unsuccessful PT performance.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT records from the CAP PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte's Total Calcium (T. Ca) and Sodium (Na) The following scores were assigned: 2022 first event = 60% This is considered unsatisfactory PT performance.</p>
D2097	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing 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 and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte's Amylase and CL The following scores were assigned: Amylase 2021 third event = 0% (failure to participate) 2022 first event = 0% (failure to participate) Chloride 2021 third event = 60% 2022 first event = 40% This is considered unsuccessful PT performance.</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte's T3 Uptake, T3, T4. The following</p>

	<p>scores were assigned: 2021 third event = 0% 2022 first event = 0% This is considered unsuccessful PT performance.</p>
D2108	<p>ENDOCRINOLOGY CFR(s): 493.843(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT records from CAP PT program, the laboratory failed to participate successfully in proficiency testing for the speciality Endocrinology. The following scores were assigned: 2021 third event = 57% 2022 first event = 51% This is considered unsuccessful PT performance.</p>
D2118	<p>TOXICOLOGY CFR(s): 493.845(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT records from CAP PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte Lithium. The following scores were assigned: 2021 third event = 0% [failure to participate] 2022 first event = 0% [failure to participate] This is considered unsuccessful PT performance.</p>
D2119	<p>TOXICOLOGY CFR(s): 493.845(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT records from CAP PT program, the laboratory failed to participate successfully in proficiency testing for the speciality Toxicology The following scores were assigned: 2021 third event = 0% [failure to participate] 2022 first event = 0% [failure to participate] This is considered unsuccessful PT performance.</p>
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a</p>

proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on PT desk review of the CMS PT data reports and PT summary reports from CAP PT program, the laboratory failed to participate successfully in CMS approved proficiency testing program, for the speciality Hematology and the test analyte's White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Cell Identification (Cell I.D.), Hemoglobin (Hgb), Hematocrit (Hct) and Platelet Count. The following scores were assigned: 2021 third event = 0% (failure to participate) This is considered unsatisfactory PT performance.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on PT desk review of the CMS PT data reports and CAP PT program records, 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, approved by CMS, for the specialities Endocrinology, General Immunology and Toxicology and the test analyte's IgE, Amylase, CL, T3 Uptake, T3, T4, Lithium, AFP, T. Ca, Na, WBC, RBC, Cell I.D., Hgb, Hct and Platelet Count. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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;

This STANDARD is not met as evidenced by:
Based on PT desk review of the CMS PT data reports and CAP PT program records, 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, approved by CMS, for the specialities Endocrinology, General Immunology and Toxicology and the test analyte's IgE, Amylase, CL, T3 Uptake, T3, T4, Lithium, AFP, T. Ca, Na, WBC, RBC, Cell I.D., Hgb, Hct and Platelet Count. The following scores were assigned: IgE, Amylase, T3 Uptake, T3, T4, Lithium and the speciality Toxicology 2021 third event = 0% (failure to participate) 2022 first event = 0% (failure to participate) Speciality Endocrinology

2021 third event = 57% 2022 first event = 51% Chloride 2021 third event = 60% 2022 first event = 40% This is considered unsuccessful PT performance. Speciality General Immunology. 2021 third event = 56% AFP,WBC,RBC, Cell I.D., Hgb, Hct and Platelet Count. 2021 third event = 0% (failure to participate) T. Ca and Na 2022 third event = 60% This is considered unsatisfactory PT performance