

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1065032	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier Fem Centre	Street Address, City, State 6221 Colleyville Blvd, Suite 100, Colleyville, TX	
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 Successful participation in a proficiency testing program 493.807 Condition: Reinstatement of laboratories performing nonwaived testing 493.1403 Laboratory Director, Moderate Complexity
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 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.</p>

This CONDITION is not met as evidenced by:
Based on a desk review of proficiency testing records, it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of Endocrinology for the Triiodothyronine analyte. Refer to D2107.

D2017

REINSTATEMENT OF NONWAIVED LABORATORIES
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:
Based on a desk review of Centers for Medicare and Medicaid Services (CMS) form 0155 and College of American Pathologists (CAP) proficiency testing records, it was determined the laboratory had not successfully participated in proficiency testing for the satisfactory performance in the specialty of Endocrinology for the Triiodothyronine (T3) analyte for two of three consecutive testing events and has not demonstrated sustained satisfactory performance on two consecutive proficiency events since the unsuccessful scores. Findings included: 1. Review of the CMS 0155 report revealed the following results: CAP 2019 -- 3rd Event laboratory received an unsatisfactory score of 0% Triiodothyronine. CAP 2020 - 1st Event laboratory received an unsatisfactory score of 0% Triiodothyronine. CAP 2020 -- 3rd Event laboratory received an unsatisfactory score of 0% Triiodothyronine. 2. Review of the laboratory's CAP proficiency testing records revealed the following results: CAP K-C 2019 Ligand General - 3rd Event laboratory received an unsatisfactory score of 0% for Triiodothyronine CAP K-A 2020 Ligand General - 1st Event laboratory received an unsatisfactory score 0% for Triiodothyronine CAP K-C 2020 Ligand General - 3rd Event laboratory received an unsatisfactory score of 0% for Triiodothyronine 3. The laboratory must demonstrate sustained satisfactory performance ($\geq 80\%$) on two consecutive testing events for reinstatement. Note: Noninitial unsuccessful participation was cited on 07/09/2020. Review of the CMS 0155 report revealed the following results for CAP proficiency testing: CAP 2019- 3rd Event laboratory received an unsatisfactory score of 0% Triiodothyronine. CAP 2020- 1st Event laboratory received an unsatisfactory score of 0% Triiodothyronine. CAP 2020- 3rd Event laboratory received an unsatisfactory score of 0% Triiodothyronine.

D2098

ENDOCRINOLOGY
CFR(s): 493.843(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 review of the CMS (Center for Medicare and Medicaid Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020, it was revealed the laboratory failed to attain a satisfactory score of at least 80% of acceptable responses for the Triiodothyronine analyte in the specialty of Endocrinology. Findings included: 1. A review of the CMS (Center for Medicare and Medicaid Services) 0155 report revealed the following results: CAP 2019 -- 3rd Event laboratory received an unsatisfactory score of 0% Triiodothyronine. CAP 2020 - 1st Event laboratory received an unsatisfactory score of 0% Triiodothyronine. CAP 2020 -- 3rd Event laboratory received an unsatisfactory score of 0% Triiodothyronine. 2. A proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020 confirmed the laboratory received the following results: CAP K-C 2019 Ligand General - 3rd Event laboratory received an unsatisfactory score of 0% for Triiodothyronine CAP K-A 2020 Ligand General - 1st Event laboratory received an unsatisfactory score 0% for Triiodothyronine CAP K-C 2020 Ligand General - 3rd Event laboratory received an unsatisfactory score of 0% for Triiodothyronine

D2099

ENDOCRINOLOGY
CFR(s): 493.843(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 review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020, it was revealed the laboratory failed to attain a satisfactory score of at least 80% for the overall event in the specialty of Endocrinology. Findings included: 1. A review of the CMS (Center for Medicare and Medicaid Services) 0155 report revealed the following results: CAP 2019 -- 3rd Event laboratory received an overall unsatisfactory score 75% for Endocrinology. CAP 2020 -- 1st Event laboratory received an overall unsatisfactory score 70% for Endocrinology. CAP 2020 -- 3rd Event laboratory received an overall unsatisfactory score of 70% for Endocrinology. 2. A proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020 confirmed the laboratory received the following results: CAP K-C 2019 Ligand General -- 3rd Event laboratory received an overall unsatisfactory score 75% for Endocrinology CAP K-A 2020 Ligand General - 1st Event laboratory received an overall unsatisfactory score 70% for Endocrinology. CAP K-C 2020 Ligand General - 3rd Event laboratory received an overall unsatisfactory score of 70% for Endocrinology.

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 review of the CMS (Center for Medicare and Medicaid Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020, it was determined that the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance in the specialty of Endocrinology for the analyte Triiodothyronine. Two out of three unsatisfactory scores result in unsuccessful Proficiency Testing (PT) performance. Findings included: 1. A review of the CMS (Center for Medicare and Medicaid Services) 0155 report revealed the following results: CAP 2019 -- 3rd Event laboratory received an overall unsatisfactory score 75% for Endocrinology. CAP 2020 -- 1st Event laboratory received an overall unsatisfactory score 70% for Endocrinology. CAP 2020 -- 3rd Event laboratory received an overall unsatisfactory score of 70% for Endocrinology. 2. A proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020 confirmed the laboratory received the following results: CAP K-C 2019 Ligand General -- 3rd Event laboratory received an overall unsatisfactory score 75% for Endocrinology CAP K-A 2020 Ligand General - 1st Event laboratory received an overall unsatisfactory score 70% for Endocrinology. CAP K-C 2020 Ligand General - 3rd Event laboratory received an overall unsatisfactory score of 70% for Endocrinology.

D2108

ENDOCRINOLOGY

CFR(s): 493.843(g)

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.

This STANDARD is not met as evidenced by:

Based on a review of the CMS (Center for Medicare and Medicaid Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same testing event in two consecutive testing events or two out of three consecutive testing events in the specialty of Endocrinology. Two out of three unsatisfactory scores result in unsuccessful PT performance. Findings included: 1. A review of the CMS (Center for Medicare and Medicaid Services) 0155 report revealed the following results: CAP 2020 -- 1st Event laboratory received an overall unsatisfactory score 70% for Endocrinology. CAP 2020 -- 3rd Event laboratory received an overall unsatisfactory score of 70% for Endocrinology. 2. A proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2019-2020 confirmed the laboratory received the following results: CAP K-A 2020 Ligand General - 1st Event laboratory received an overall unsatisfactory score 70% for Endocrinology. CAP K-C 2020 Ligand General - 3rd Event laboratory received an overall unsatisfactory score of 70% for Endocrinology.

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 a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. 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 a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2107 and D2108.