Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503810	06/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mission Pediatric Center	210 South Bryan Road Suite 5a, Mission, 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	Based on a proficiency testing desk review survey performed on June 17, 2021, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the facility failed to achieve successful

	performance in two of three consecutive testing events for the analytes Red Blood Cells and Platelets, resulting in unsuccessful performance (refer to D2121 and D2130).
D2121	HEMATOLOGY CFR(s): 493.851(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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) evaluation report, the facility failed to attain a score of at least 80 percent for the analytes Red Blood Cell (RBC) and Platelets in two of three consecutive testing events in 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) evaluation reports, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the analytes Red Blood Cell (RBC) and Platelets in the specialty of Hematology in two of three consecutive events: RBC - 2020 API 3rd event 40% RBC - 2021 API 1st event 0% Platelets - 2020 API 3rd event 40% Platelets - 2021 API 1st event 0%
D2122	HEMATOLOGY CFR(s): 493.851(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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) evaluation report, the facility failed to participate in the 1st event of 2021 resulting in a score of 0% for the overall hematology testing event score. The findings included: 1. API 2020 - 3rd event reported a hematology testing event score of 76% 2. API 2021 - 1st event reported a hematology testing event score of 0%. Failure to attain an overall testing event score of at least 80% is unsatisfactory 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. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) evaluation report, the laboratory failed to participate in event 1 of 2021 for the specialty of hematology. An unacceptable score of zero, results in unsuccessful performance. The findings included: 1. API reported "failure to participate" in event 1 of 2021 resulting in a score of 0% for all analytes in the specialty of hematology. White Blood Cell differential 0% RBC score 0% Hematocrit score 0% Hemoglobin score 0% White Blood Cells score 0% Platelets score 0% Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) evaluation reports, the facility failed achieve satisfactory performance for the analytes Red Blood Cell (RBC) and Platelets in two of three consecutive testing events in 2020 and 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) evaluation reports, the laboratory received the following unsuccessful performance for the analytes RBC and Platelets in the specialty of Hematology in two of three consecutive events: RBC - 2020 API 3rd event 40% RBC - 2021 API 1st event 0% Platelets - 2020 API 3rd event 40% Platelets - 2021 API 1st event 0% Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Platelet count in the specialty of Hematology (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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and College of American Pathologists (CAP) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Platelet count in the specialty of Hematology (refer to D2016).