Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2072399	02/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
1st Choice Pediatrics	1205 North 6th Street, Longview, 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 national database and verified with the proficiency testing company. 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: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2017 - 42 C.F.R. 493.807 (a) - Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
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 a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records and American Proficiency Institute (API) from 2019-2020, it was determined the laboratory has not successfully participated in a proficiency testing program, 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 hematology for the analyte Red Cell Count (RBC); Hematocrit (HCT); Hemaglobin (Hgb); White blood count (WBC); Platelet (PLT); and Cell ID. (Refer to D2130, D2131)
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 review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019 and American Proficiency Institute proficiency testing records from 2020, it was determined the laboratory had not successfully participated in proficiency testing for the satisfactory performance in the specialty of hematology for the analytes: Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID resulting in a non-initial PT failure. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of less than 80% for the analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 3 of 3 consecutive testing events in 2019 (Events 1 and 2) and 2020 (Event 1): 2019 AAB 2nd & 3rd event RBC - 0% HCT - 0% Hgb - 0% WBC - 0% PLT - 0% Cell ID - 0% 2020 API 1st event RBC - 40% HCT - 40% Hgb - 40% WBC - 60% PLT - 20% Cell ID - 60% 2. Review of AAB and API PT records for Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID revealed the laboratory received the following scores for the 2019 2nd and 3rd AABevents, and 2020 API 1st event: 2019 AAB 2nd & 3rd event RBC - 0% HCT - 0% Hgb - 0% WBC - 0% PLT - 0% Cell ID - 0% 2020 API 1st event RBC - 40% HCT - 40% Hgb - 40% WBC - 60% PLT - 20% Cell ID - 60% 3. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement.
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 a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing (PT) records from 2019 and American Proficiency Institute (API) from 2020, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analytes: Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID for 3 of 3 consecutive testing events in 2019 (2nd and 3rd event) and 2020 (1st event). Findings were: 1. A review of the CMS national proficiency testing database revealed a score of less than 80% for the analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 3 of 3 consecutive testing events in 2019 (2nd and 3rd event) and 2020 (1st event). 2019 AAB 2nd & 3rd event RBC - 0% HCT - 0% Hgb - 0% WBC - 0% PLT - 0% Cell ID - 0% 2020 API 1st event RBC - 40% HCT - 40% Hgb - 40% WBC - 60% PLT - 20% Cell ID - 60% 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2018-2020 confirmed that the laboratory received a hematology score of 0% on for the following analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 2 of 2 consecutive testing events in 2019 for the following test events: 2019 AAB 2nd & 3rd event 3. A proficiency desk review of the API proficiency testing records from 2020 confirmed that the laboratory received the following hematology scores for the following analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 1 of 3 testing events in 2020: 2020 API 1st event RBC - 40% HCT - 40% Hgb - 40% WBC - 60% PLT - 20% Cell ID - 60%
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 a review of the CMS (Center for Medicare Services) national database and a desk review of proficiency testing records from American Board of Bioanalysts (AAB) from 2019 and American Proficiency Institute (API) from 2020, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the specialty of hematology in 3 of 3 consecutive testing events in 2019 (Events 1 and 2) and 2020 (Event 1). Findings were: 1. A review of the CMS national proficiency testing database revealed the following scores for the following Hematology testing events in 2019 and 2020: 2019 AAB 2nd & 3rd event - 0% 2020 API 1st event - 40% 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019 confirmed that the laboratory received a hematology score of 0% for 2 of 2 consecutive testing events in 2019 for the following test events: 2019 AAB 2nd & 3rd event 3. A proficiency desk review of the American Proficiency Institute (API) proficiency testing records from 2020 confirmed that the laboratory received a hematology score of 40% for 1 of 3 testing events in 2020 for the following test events: 2020 API 1st event - 40%
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 a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing (PT) records from 2019 and American Proficiency Institute (API) from 2020, it was determined the laboratory failed to achieve satisfactory performance for the same analyte in 3 of 3 consecutive testing events. The laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analytes: Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID for 3 of 3 consecutive testing events in 2019 (2nd and 3rd event) and 2020 (1st event). Findings were: 1. A review of the CMS national proficiency testing database revealed a score of less than 80% for the analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 3 of 3 consecutive testing events in 2019 (2nd and 3rd event) and 2020 (1st event). 2019 AAB 2nd & 3rd event RBC - 0% HCT - 0% Hgb - 0% WBC - 0% PLT - 0% Cell ID - 0% 2020 API 1st event RBC - 40% HCT - 40% Hgb - 40% WBC - 60% PLT - 20% Cell ID - 60% 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019 confirmed that the laboratory received a hematology score of 0% on for the following analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 2 of 2 consecutive testing events in 2019 for the following test events: 2019 AAB 2nd & 3rd event 3. A proficiency desk review of the API proficiency testing records from 2020 confirmed that the laboratory received the following hematology scores for the following analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 1 of 3 testing events in 2020: 2020 API 1st event RBC - 40% HCT - 40% Hgb - 40% WBC - 60% PLT - 20% Cell ID - 60% 4. Three out of three unsatisfactory scores of the same analytes result in unsuccessful PT performance.
D2131	HEMATOLOGY CFR(s): 493.851(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 Services) national database and a desk review of proficiency testing records from American Board of Bioanalysts (AAB) from 2019 and American Proficiency Institute (API) from 2020, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the specialty of hematology in 3 of 3 consecutive testing events. Three out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. A review of the CMS national proficiency testing database revealed the following scores for the following Hematology testing events in 2019 and 2020: 2019 AAB 2nd & 3rd event - 0% 2020 API 1st event - 40% 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019 confirmed that the laboratory received a hematology score of 0% for 2 of 2 consecutive testing events in 2019 for the following test events: 2019

	AAB 2nd & 3rd event 3. A proficiency desk review of the American Proficiency Institute (API) proficiency testing records from 2020 confirmed that the laboratory received a hematology score of 40% for 1 of 3 testing events in 2020 for the following test events: 2020 API 1st event - 40% 4. Three out of three overall testing event scores of unsatisfactory performance results in unsuccessful 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 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. Findings were: 1. A review of the laboratory proficiency testing results revealed that the laboratory director failed to ensure that the laboratory participated successfully. (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 an approved proficiency testing program. (refer to D2131and D2130)