Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2074778	05/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lodestar Diagnostic Laboratory Inc	11301 Fallbrook Drive #108, Houston, 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 from 2018-2020, 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) The laboratory did not successfully participate in the specialty of chemistry for the analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); URIC ACID; and subspecialty of ENDOCRINOLOGY for the analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). (Refer to D2096, D2097, D2107, D2108)
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: I. 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 2018-2020, 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. Review of AAB PT records for 2018-2020 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 2018 Hematology 3rd event, and 2019 2nd and 3rd events, and 2020 1st event: AAB 3rd event 2018 = 0% AAB 2nd event 2019 = 0% AAB 3rd event 2019 = 0% AAB 1st event 2020 = 0% 2. A review of the performance summary reports from AAB proficiency testing agency confirmed the laboratory failed to submit proficiency testing results which resulted in a grade of 0 for the analytes Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb), White blood count (WBC), Platelet (PLT), and Cell ID. AAB 3rd event 2018 = 0% AAB 2nd event 2019 = 0% AAB 3rd event

	2019 = 0% AAB 1st event 2020 = 0% 3. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement. II. 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 2019-2020, it was determined the laboratory had not successfully participated in proficiency testing for the satisfactory performance in the specialty of chemistry for the analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); URIC ACID; and subspecialty of ENDOCRINOLOGY for the analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone) resulting in a non-initial PT failure. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the analytes in 3 of 3 Chemistry testing events for the analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID. 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed that the laboratory received a chemistry score of 0% for 3 of 3 consecutive testing events for the following analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID. 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event 3. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement. 4. A review of the CMS national proficiency testing database revealed a score of "0" in 3 of 3 consecutive Chemistry testing events for the analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). 2019 AAB 3rd Chemistry event 2020 AAB 1st Chemistry event 2020 AAB 2nd Chemistry event 5. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed that the laboratory received an endocrinology score of 0% in 3 of 3 consective testing events for the following analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). 2019 AAB 3rd Chemistry event 2020 AAB 1st Chemistry event 2020 AAB 2nd Chemistry event 6. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 records from 2019-2020, it was revealed the laboratory failed to achieve satisfactory performance (80% or greater) for the following analytes in 3 of 3 consecutive testing events: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID. Findings were: 1. A review of the CMS (Center for Medicare Services) national database revealed the laboratory received a score of '0' for the following analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID for the following chemistry testing events. 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed the laboratory received a score of '0' for the following analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); URIC ACID for the following chemistry testing events. 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(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 American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed that the laboratory failed to attain an overall testing event score of at least 80 % for each Chemistry event which constitutes unsatisfactory performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for Chemistry on the 3rd event of 2019 and 1st and 2nd event of 2020 for this facility. 2. A proficiency desk review of proficiency testing records for 2019-2020 revealed the facility to attain an overall testing event score of at least 80 % for 3 of 3 Chemistry events. 2019 AAB 3rd event - 0% 2020 AAB 1st event - 0% 2020 AAB 2nd event - 0%
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 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 2018 - 2020, it was revealed that the laboratory failed to participate in the 3rd chemistry testing event of 2019 and 1st and 2nd chemistry events of 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the specialty of Chemistry on the 3rd event of 2019 and 1st and 2nd events of 2020 for this facility. 2. A proficiency desk review of AAB PT records revealed the laboratory received a 0% for the 2019-3rd Chemistry event; 2020-1st Chemistry event PT for "Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing events 2019-3; 2020-1; and 2020-2 Chemistry.
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 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 2019-2020, it was revealed the laboratory failed to achieve satisfactory performance (80% or greater) for the following analytes in 3 of 3 consecutive testing events: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the analytes in 3 of 3 testing events for the analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID. 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed that the laboratory received a chemistry score of 0% for 3 of 3 consecutive testing events for the following analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride);

	CHOLESTEROL; HDL (high-density lipoprotein); CK (Creatine kinase); TOTAL CREATINE; GLUCOSE; MG (Magnesium); K (potassium); NA (Sodium); TOTAL PROTEIN; TRIGL (Triglyceride); BUN (Urea nitrogen); and URIC ACID. 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(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 proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for 3 of 3 consecutive testing events for the specialty of chemistry. Two 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 a score of "0" for the 2019 AAB Chemistry 3rd event and 2020 AAB Chemistry 1st and 2nd events. 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed that the laboratory received a chemistry score of 0% for the 2019 AAB Chemistry 3rd event and 2020 AAB Chemistry 1st and 2nd events.
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 Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to achieve satisfactory performance (80% or greater) for the following analytes in 3 of 3 consecutive testing events: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). Findings were: 1. A review of the CMS (Center for Medicare Services) national database revealed the laboratory received a score of '0' for the following analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed the laboratory received a score of '0' for the following analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). 2019 AAB 3rd event 2020 AAB 1st event 2020 AAB 2nd event
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 American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed that the laboratory failed to attain an overall testing event score of at least 80 % for 3 of 3 Endocrinology events which constitutes unsatisfactory performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for Endocrinology on the 3rd event of 2019 and 1st and 2nd events of of 2020 for this facility. 2. A proficiency desk review of proficiency testing records for 2019-2020 revealed the facility to attain an overall testing event score of at least 80 % for 3 of 3 Endocrinology events. 2019 AAB 3rd event - 0% 2020 AAB 1st event - 0% 2020 AAB 2nd event - 0%
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 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 - 2020, it was revealed that the laboratory failed to participate in the 3rd endocrinology testing event of 2019 and 1st and 2nd endocrinology events of 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the subspecialty of endocrinology on the 3rd event of 2019 and 1st and 2nd events of 2020 for this facility. 2. A review of AAB PT records revealed the laboratory received a 0% for the subspecialty of endocrinology for the 2019-3rd Chemistry event; 2020-1st Chemistry ; 2020-2 event PT for "Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing events 2019-3; 2020-1; and 2020-2 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 Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to achieve satisfactory performance (80% or greater) for the following analytes in 3 of 3 consecutive testing events: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" in 3 of 3 consecutive testing events for the analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). 2019 AAB 3rd Chemistry event 2020 AAB 1st Chemistry event 2020 AAB 2nd Chemistry event 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed that the laboratory received an endocrinology score of 0% in 3 of 3 consective testing events for the following analytes: FREE TY (Free thyroxine); HCG (Human chorionic gonadotropin); and TSH (thyroid stimulating hormone). 2019 AAB 3rd Chemistry event 2020 AAB 1st Chemistry event 2020 AAB 2nd Chemistry event
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 Services) national database and a proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for 3 of 3 consecutive testing events for the subspecialty of Endocrinology. Two 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 a score of "0" for subspecialty of Endocrinology for the 2019 AAB 3rd Chemistry event and 2020 AAB Chemistry 1st and 2nd events. 2. A proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2019-2020 confirmed that the laboratory received an Endocrinology score of 0% for the 2019 AAB Chemistry 3rd event and 2020 AAB Chemistry 1st and 2nd events.
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 records from 2018-2020, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analytes: analyte Red Cell Count (RBC), Hematocrit (HCT), Hemaglobin (Hgb),

	White blood count (WBC), Platelet (PLT), and Cell ID for 4 of 5 consecutive testing events in 2018, 2019, and 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 4 of 5 consecutive testing events in 2018, 2019, and 2020 for the following test events: 2018 AAB 3rd event 2019 AAB 2nd & 3rd event 2020 AAB 1st event 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 the following testing events: 2018 AAB 3rd event 2019 AAB 2nd & 3rd event 2020 AAB 1st event
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 proficiency desk review of the American Board of Bioanalysts (AAB) proficiency testing records from 2018-2020, it was determined the laboratory failed to attain an overall testing event score of at least 80 % for 4 of 5 Hematology test events which constitutes unsatisfactory performance. Findings were: 1. A proficiency desk review of 4 of 5 AAB Hematology proficiency testing records from 2018-2020 revealed a hematology event score of less than 80% (unsatisfactory performance) for the following testing events: 2018 AAB 3rd event Hematology: 0% 2019 AAB 2nd & 3rd event Hematology: 0% 2020 AAB 1st event: Hematology: 0%
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 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 2018 - 2020, it was revealed that the laboratory failed to participate in the 3rd hematology testing events of 2018; 2nd and 3rd hematology event of 2019; and 1st hematology event of 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" on the 3rd event of 2018; 2nd and 3rd hematology event of 2019; and 1st event of 2020 for this facility. 2. A proficiency desk review of AAB PT records revealed the laboratory received a 0% for the Hematology 2018-3rd event; 2019-2nd and 2019-3rd event; 2020-1st event PT

	for "Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing events 2018-3, 2019-2; 2019-3; and 2020-1 Hematology.
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 records from 2018-2020, it was determined the laboratory failed to achieve satisfactory performance for the same analyte in 4 of 5 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 4 of 5 consecutive testing events in 2018, 2019, and 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the analytes: RBC, HCT, Hgb, WBC, PLT, and Cell ID for 4 of 5 consecutive testing events in 2018, 2019, and 2020 for the following test events: 2018 AAB 3rd event 2019 AAB 2nd & 3rd event 2020 AAB 1st event 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 4 of 5 consecutive testing events in 2018, 2019, and 2020 for the following test events: 2018 AAB 3rd event 2019 AAB 2nd & 3rd event 2020 AAB 1st event
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, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the specialty of hematology in 4 of 5 consecutive testing events. Two 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 a score of "0" for 4 of 5 consecutive Hematology testing events in 2018, 2019, and 2020 for the following test events: 2018 AAB 3rd event 2019 AAB 2nd & 3rd event 2020 AAB 1st event 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% for 4 of 5 consecutive testing events in 2018, 2019, and 2020 for the following test events: 2018 AAB 3rd event 2019 AAB 2nd & 3rd event 2020 AAB 1st event

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) By not providing overall management and direction of the laboratory, the laboratory director could not ensure the accuracy or reliability of all laboratory services provided by the facility.
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 D2097, D2108, D2131, D2096, D2107, and D2130)