

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2161589	(X3) Date Survey Completed 08/01/2022
Name of Provider or Supplier Exam Corp Lab	Street Address, City, State 9024 N Milwaukee Ave, Niles, IL	
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
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> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the American Association of Bioanalysts (AAB) PT program representative the laboratory's SUBSEQUENT unsuccessful PT performance for the specialties of chemistry (See D2097) and hematology (See D2131) and the following analytes: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), total bilirubin, total calcium (CA), chloride (CL), total cholesterol, high-density lipoprotein (HDL) cholesterol, total creatine kinase (CK), creatine, glucose, total iron, total lactate dehydrogenase (LDH), magnesium (MG), potassium (K), sodium (NA), total protein, triglycerides (TRIGL),</p>

blood urea nitrogen (BUN), uric acid (See D2096), cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets (See D2130) was confirmed for PT event three of 2020, event one of 2021, and events one and two of 2022.

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 review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the PT provider American Association of Bioanalysts (AAB) program representative the laboratory's SUBSEQUENT unsuccessfully PT performance for the routine chemistry analytes alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), aspartate aminotransferase (AST), total bilirubin, total calcium (CA), chloride (CL), total cholesterol, creatine, glucose, potassium (K), sodium (NA), total protein, triglycerides (TRIGL), blood urea nitrogen (BUN), and uric acid was confirmed for PT event three of 2020, event one of 2021, and events one and two of 2022. Findings include: 1. Review of the CASPER Report 0155D, generated on 08-01-2022, identified the SUBSEQUENT unsuccessful performance for the routine chemistry analytes identified below. ROUTINE CHEMISTRY ALT - EVENT 3, 2020 - 0% Unsatisfactory ALT - EVENT 1, 2021 - 0% Unsatisfactory ALT - EVENT 1, 2022 - 0% Unsatisfactory ALT - EVENT 2, 2022 - 0% Unsatisfactory Albumin - EVENT 3, 2020 - 0% Unsatisfactory Albumin - EVENT 1, 2021 - 0% Unsatisfactory Albumin - EVENT 1, 2022 - 0% Unsatisfactory Albumin - EVENT 2, 2022 - 0% Unsatisfactory ALP - EVENT 3, 2020 - 0% Unsatisfactory ALP - EVENT 1, 2021 - 0% Unsatisfactory ALP - EVENT 1, 2022 0% - Unsatisfactory ALP - EVENT 2, 2022 0% - Unsatisfactory AST - EVENT 3, 2020 - 0% Unsatisfactory AST - EVENT 1, 2021 - 0% Unsatisfactory AST- EVENT 1, 2022 0% - Unsatisfactory AST- EVENT 2, 2022 0% - Unsatisfactory Total Bilirubin - EVENT 3, 2020 - 0% Unsatisfactory Total Bilirubin- EVENT 1, 2021 - 0% Unsatisfactory Total Bilirubin - EVENT 1, 2022 0% - Unsatisfactory Total Bilirubin - EVENT 2, 2022 0% - Unsatisfactory Total Calcium - EVENT 3, 2020 - 0% Unsatisfactory Total Calcium - EVENT 1, 2021 - 0% Unsatisfactory Total Calcium - EVENT 1, 2022 0% - Unsatisfactory Total Calcium - EVENT 2, 2022 0% - Unsatisfactory Chloride - EVENT 3, 2020 - 0% Unsatisfactory Chloride - EVENT 1, 2021 - 0% Unsatisfactory Chloride - EVENT 1, 2022 0% - Unsatisfactory Chloride - EVENT 2, 2022 0% - Unsatisfactory Total Cholesterol - EVENT 3, 2020 - 0% Unsatisfactory Total Cholesterol - EVENT 1, 2021 - 0% Unsatisfactory Total Cholesterol - EVENT 1, 2022 0% - Unsatisfactory Total Cholesterol - EVENT 2, 2022 0% - Unsatisfactory Creatine - EVENT 3, 2020 - 0% Unsatisfactory Creatine - EVENT 1, 2021 - 0% Unsatisfactory Creatine - EVENT 1, 2022 0% - Unsatisfactory Creatine - EVENT 2, 2022 0% - Unsatisfactory Glucose - EVENT 3, 2020 - 0% Unsatisfactory Glucose - EVENT 1, 2021 - 0% Unsatisfactory Glucose - EVENT 1, 2022 0% - Unsatisfactory Glucose - EVENT 2, 2022 0% - Unsatisfactory K - EVENT 3, 2020 - 0% Unsatisfactory K - EVENT 1, 2021 - 0% Unsatisfactory K - EVENT 1, 2022 0% - Unsatisfactory K - EVENT 2, 2022 0% - Unsatisfactory NA - EVENT 3, 2020 - 0% Unsatisfactory NA - EVENT 1, 2021 - 0% Unsatisfactory NA - EVENT 1, 2022 0% - Unsatisfactory NA - EVENT 2, 2022 0% - Unsatisfactory Total Protein - EVENT 3, 2020 - 0% Unsatisfactory Total Protein -

EVENT 1, 2021 - 0% Unsatisfactory Total Protein - EVENT 1, 2022 0% - Unsatisfactory Total Protein - EVENT 2, 2022 0% - Unsatisfactory TRIGL - EVENT 3, 2020 - 0% Unsatisfactory TRIGL - EVENT 1, 2021 - 0% Unsatisfactory TRIGL - EVENT 1, 2022 0% - Unsatisfactory TRIGL - EVENT 2, 2022 0% - Unsatisfactory BUN - EVENT 3, 2020 - 0% Unsatisfactory BUN - EVENT 1, 2021 - 0% Unsatisfactory BUN - EVENT 1, 2022 0% - Unsatisfactory BUN - EVENT 2, 2022 0% - Unsatisfactory Uric Acid - EVENT 3, 2020 - 0% Unsatisfactory Uric Acid - EVENT 1, 2021 - 0% Unsatisfactory Uric Acid - EVENT 1, 2022 0% - Unsatisfactory Uric Acid - EVENT 2, 2022 0% - Unsatisfactory 2. A phone interview with the (AAB) PT representative on 08/01/2022 at 10:18 AM, confirmed the subsequent unsuccessful PT performance for the routine chemistry analytes alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), aspartate aminotransferase (AST), total bilirubin, total calcium (CA), chloride (CL), total cholesterol, creatine, glucose, potassium (K), sodium (NA), total protein, triglycerides (TRIGL), blood urea nitrogen (BUN), and uric acid for PT event three of 2020, event one of 2021, and events one and two of 2022.

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 review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the PT provider American Association of Bioanalysts (AAB) program representative the SUBSEQUENT unsuccessful PT performance for the specialty of routine chemistry was confirmed for PT event 3 of 2020, event 1 of 2021, and events one and two of 2022. Findings include: 1. Review of the CASPER Report 0155D, generated on 08-01-2022, identified the subsequent unsuccessful performance for the specialty of routine chemistry. ROUTINE CHEMISTRY - EVENT 3, 2020 0% Unsatisfactory ROUTINE CHEMISTRY - EVENT 1, 2021 0% Unsatisfactory ROUTINE CHEMISTRY - EVENT 1, 2022 0% Unsatisfactory ROUTINE CHEMISTRY - EVENT 2, 2022 27% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 08/01/2022 at 10:18 AM, confirmed the subsequent unsuccessful performance for the specialty of routine chemistry for PT event 3 of 2020, event 1 of 2021, and events one and two of 2022.

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 CASPER Report 0155D Proficiency Testing (PT) records and interview with the PT provider American Association of Bioanalysts (AAB) program representative the subsequent unsuccessful PT performance for the hematology analytes cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets was confirmed for PT event three of

2020, event one of 2021, and events one and two of 2022. Findings include: 1. Review of the CASPER Report 0155D, generated on 08-01-2022, revealed the subsequent unsuccessful performance for the hematology analytes identified below. HEMATOLOGY Cell Identification/White Blood Cell Differential - EVENT 3, 2020 0% Unsatisfactory Cell Identification/White Blood Cell Differential - EVENT 1, 2021 0% Unsatisfactory Cell Identification/White Blood Cell Differential - EVENT 1, 2022 0% Unsatisfactory Cell Identification/White Blood Cell Differential - EVENT 2, 2022 0% Unsatisfactory Red Blood Cells- EVENT 3, 2020 0% Unsatisfactory Red Blood Cells- EVENT 1, 2021 0% Unsatisfactory Red Blood Cells - EVENT 1, 2022 0% Unsatisfactory Red Blood Cells - EVENT 2, 2022 0% Unsatisfactory Hematocrit - EVENT 3, 2020 0% Unsatisfactory Hematocrit - EVENT 1, 2021 0% Unsatisfactory Hematocrit - EVENT 1, 2022 0% Unsatisfactory Hematocrit - EVENT 2, 2022 0% Unsatisfactory Hemoglobin - EVENT 3, 2020 0% Unsatisfactory Hemoglobin - EVENT 1, 2021 0% Unsatisfactory Hemoglobin - EVENT 1, 2022 0% Unsatisfactory Hemoglobin - EVENT 2, 2022 0% Unsatisfactory White Blood Cells - EVENT 3, 2020 0% Unsatisfactory White Blood Cells - EVENT 1, 2021 0% Unsatisfactory White Blood Cells - EVENT 1, 2022 0% Unsatisfactory White Blood Cells - EVENT 2, 2022 0% Unsatisfactory Platelets - EVENT 3, 2020 0% Unsatisfactory Platelets - EVENT 1, 2021 0% Unsatisfactory Platelets - EVENT 1, 2022 0% Unsatisfactory Platelets - EVENT 2, 2022 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 08/01/2022 at 10:18 AM, confirmed the subsequent unsuccessful PT performance for the hematology analytes cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets for PT event three of 2020, event one of 2021, and events one and two of 2022.

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 review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the PT provider American Association of Bioanalysts (AAB) program representative the SUBSEQUENT unsuccessful PT performance for the specialty of hematology was confirmed for PT event 3 of 2020, event 1 of 2021, and events one and two of 2022. Findings include: 1. Review of the CASPER Report 0155D, generated on 08-01-2022, identified the subsequent unsuccessful performance for the specialty of hematology. HEMATOLOGY - EVENT 3, 2020 0% Unsatisfactory HEMATOLOGY - EVENT 1, 2021 0% Unsatisfactory HEMATOLOGY - EVENT 1, 2022 0% Unsatisfactory HEMATOLOGY - EVENT 2, 2022 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 08/01/2022 at 10:18 AM, confirmed the subsequent unsuccessful performance for the specialty of hematology for event 3 of 2020, event 1 of 2021, and events one and two of 2022.

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 review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the American Association of Bioanalysts (AAB) PT program representative the laboratory director failed to ensure the laboratory enrolled in event 1 of 2022 AAB PT (See D6015) and failed to ensure the laboratory submitted PT results to AAB for PT event two of 2022 (see D6016) resulting in the laboratory's SUBSEQUENT unsuccessful PT performance for the specialties of chemistry and hematology and the following analytes: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), total bilirubin, total calcium (CA), chloride (CL), total cholesterol, high-density lipoprotein (HDL) cholesterol, total creatine kinase (CK), creatine, glucose, total iron, total lactate dehydrogenase (LDH), magnesium (MG), potassium (K), sodium (NA), total protein, triglycerides (TRIGL), blood urea nitrogen (BUN), uric acid, cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets.

D6015

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

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the American Association of Bioanalysts (AAB) PT program representative the laboratory director failed to ensure the laboratory maintained enrollment for PT event one of 2022 contributing to the SUBSEQUENT unsuccessful PT performance for the specialties of chemistry and hematology and the following analytes: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), total bilirubin, total calcium (CA), chloride (CL), total cholesterol, high-density lipoprotein (HDL) cholesterol, total creatine kinase (CK), creatine, glucose, total iron, total lactate dehydrogenase (LDH), magnesium (MG), potassium (K), sodium (NA), total protein, triglycerides (TRIGL), blood urea nitrogen (BUN), uric acid, cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets. Findings Include: 1. Review of the CASPER Report 0155D, generated on 08-01-2022, identified the 0% unsatisfactory scores for PT event one of 2022. (See D2096, D2097, D2130, D2131) 2. A phone interview with the (AAB) PT representative on 08-01-2022 at 10:18 AM, confirmed the laboratory failed to pay for their PT enrollment with AAB prior to the cut-off date for PT event one of 2022 shipment, resulting in the laboratory receiving scores of 0% for all analytes.

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 review of the CASPER Report 0155D Proficiency Testing (PT) records and interview with the American Association of Bioanalysts (AAB) PT program representative the laboratory director failed to ensure the laboratory submitted results for PT event two of 2022 contributing to the SUBSEQUENT unsuccessful PT performance for the specialties of chemistry and hematology and the following analytes: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), total bilirubin, total calcium (CA), chloride (CL), total cholesterol, high-density lipoprotein (HDL) cholesterol, total creatine kinase (CK), creatine, glucose, total iron, total lactate dehydrogenase (LDH), magnesium (MG), potassium (K), sodium (NA), total protein, triglycerides (TRIGL), blood urea nitrogen (BUN), uric acid, cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets. Findings Include: 1. Review of the CASPER Report 0155D, generated on 08-01-2022, identified the 0% unsatisfactory scores for PT event two of 2022. (See D2096, D2097, D2130, D2131) 2. A phone interview with the (AAB) PT representative on 08-01-2022 at 10:18 AM, confirmed the laboratory failed to submit PT results for PT event two of 2022 for hematology and routine chemistry analytes.