

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2161589	(X3) Date Survey Completed 05/06/2021
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 communication with the American Association of Bioanalysts (AAB) PT program representative; the laboratory failed to successfully participate in the testing of PT samples for the specialties of chemistry and hematology for event 3 of 2020 and event 1 of 2021. Findings include: 1. Review of CASPER Report 0155D (generated on 5-03-2021) and communication with the (AAB) PT provider on 05/06/2021 at 8:37 AM, confirmed the initial unsuccessful performance for the sub-specialty routine chemistry analytes alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), total bilirubin, total calcium (CA),</p>

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), and uric acid for event 3 of 2020 and event 1 of 2021. See D2096. 2. Review of CASPER Report 0155D (generated on 5-03-2021) and communication with the (AAB) PT provider on 05/06/2021 at 8:37 AM, confirmed the initial unsuccessful performance for the sub-specialty routine chemistry for event 3 of 2020 and event 1 of 2021. See D2097. 3. Review of CASPER Report 0155D (generated on 5-03-2021) and communication with the (AAB) PT provider on 05/06/2021 at 8:37 AM, confirmed the initial unsuccessful performance for the specialty hematology analytes cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets for event 3 of 2020 and event 1 of 2021. See D2130. 4. Review of CASPER Report 0155D (generated on 5-03-2021) and communication with the (AAB) PT provider on 05/06/2021 at 8:37 AM, confirmed the initial unsuccessful performance for the specialty of hematology for event 3 of 2020 and event 1 of 2021. See D2131.

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 communication with the PT provider American Association of Bioanalysts (AAB) program representative; the laboratory failed to successfully participate in the testing of the routine chemistry 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), and uric acid for event 3 of 2020 and event 1 of 2021. Findings include: 1. Review of the CASPER Report 0155D, generated on 05-03-2021, identified the initial unsuccessful performance for the routine chemistry analytes identified below. ROUTINE CHEMISTRY ALT - EVENT 3, 2020 0% Unsatisfactory ALT - EVENT 1, 2021 0% Unsatisfactory Albumin - EVENT 3, 2020 0% Unsatisfactory Albumin - EVENT 1, 2021 0% Unsatisfactory ALP - EVENT 3, 2020 0% Unsatisfactory ALP - EVENT 1, 2021 0% Unsatisfactory Amylase - EVENT 3, 2020 0% Unsatisfactory Amylase - EVENT 1, 2021 0% Unsatisfactory AST- EVENT 3, 2020 0% Unsatisfactory AST - EVENT 1, 2021 0% Unsatisfactory Total Bilirubin - EVENT 3, 2020 0% Unsatisfactory Total Bilirubin - EVENT 1, 2021 0% Unsatisfactory Total Calcium - EVENT 3, 2020 0% Unsatisfactory Total Calcium - EVENT 1, 2021 0% Unsatisfactory Chloride - EVENT 3, 2020 0% Unsatisfactory Chloride - EVENT 1, 2021 0% Unsatisfactory Total Cholesterol - EVENT 3, 2020 0% Unsatisfactory Total Cholesterol - EVENT 1, 2021 0% Unsatisfactory HDL Cholesterol - EVENT 3, 2020 0% Unsatisfactory HDL Cholesterol - EVENT 1, 2021 0% Unsatisfactory Total CK - EVENT 3, 2020 0% Unsatisfactory Total CK - EVENT 1, 2021 0% Unsatisfactory Creatine- EVENT 3, 2020 0% Unsatisfactory Creatine - EVENT 1, 2021 0% Unsatisfactory Glucose - EVENT 3, 2020 0% Unsatisfactory Glucose - EVENT 1, 2021 0% Unsatisfactory

Total Iron - EVENT 3, 2020 0% Unsatisfactory Total Iron - EVENT 1, 2021 0% Unsatisfactory Total LDH - EVENT 3, 2020 0% Unsatisfactory Total LDH - EVENT 1, 2021 0% Unsatisfactory MG - EVENT 3, 2020 0% Unsatisfactory MG - EVENT 1, 2021 0% Unsatisfactory K - EVENT 3, 2020 0% Unsatisfactory K - EVENT 1, 2021 0% Unsatisfactory NA - EVENT 3, 2020 0% Unsatisfactory NA - EVENT 1, 2021 0% Unsatisfactory Total Protein - EVENT 3, 2020 0% Unsatisfactory Total Protein - EVENT 1, 2021 0% Unsatisfactory TRIGL - EVENT 3, 2020 0% Unsatisfactory TRIGL - EVENT 1, 2021 0% Unsatisfactory BUN - EVENT 3, 2020 0% Unsatisfactory BUN - EVENT 1, 2021 0% Unsatisfactory Uric Acid - EVENT 3, 2020 0% Unsatisfactory Uric Acid - EVENT 1, 2021 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 05/06/2021 at 8:37 AM, confirmed the unsatisfactory scores for the routine chemistry analytes ALT, albumin, ALP, amylase, AST, total bilirubin, total CA, CL, total cholesterol, HDL cholesterol, total CK, creatine, glucose, total iron, total LDH, MG, K, NA, total protein, TRIGL, BUN, and uric acid for event 3 of 2020 and event 1 of 2021.

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 communication with the PT provider American Association of Bioanalysts (AAB) program representative; the laboratory failed to successfully participate in the testing of the sub-specialty routine chemistry for event 3 of 2020 and event 1 of 2021. Findings include: 1. Review of the CASPER Report 0155D, generated on 05-03-2021, revealed the initial unsuccessful performance for the sub-specialty of routine chemistry. ROUTINE CHEMISTRY - EVENT 3, 2020 0% Unsatisfactory ROUTINE CHEMISTRY - EVENT 1, 2021 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 05/06/2021 at 8:37 AM, confirmed the unsuccessful performance for the sub-specialty of routine chemistry for event 3 of 2020 and event 1 of 2021.

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 communication with the PT provider American Association of Bioanalysts (AAB) program representative; the laboratory failed to successfully participate in the testing of the hematology analytes cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets for event 3 of 2020 and event 1 of 2021. Findings include: 1. Review of the CASPER Report 0155D, generated on 05-03-2021, revealed the initial 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 Red Blood Cells- EVENT 3, 2020 0% Unsatisfactory Red Blood Cells- EVENT 1, 2021 0% Unsatisfactory Hematocrit - EVENT 3, 2020 0% Unsatisfactory Hematocrit- EVENT 1, 2021 0% Unsatisfactory Hemoglobin - EVENT 3, 2020 0% Unsatisfactory Hemoglobin- EVENT 1, 2021 0% Unsatisfactory White Blood Cells- EVENT 3, 2020 0% Unsatisfactory White Blood Cells- EVENT 1, 2021 0% Unsatisfactory Platelets- EVENT 3, 2020 0% Unsatisfactory Platelets- EVENT 1, 2021 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 05/06/2021 at 8:37 AM, confirmed the unsatisfactory scores for the hematology analytes cell identification /white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets for event 3 of 2020 and event 1 of 2021.

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 communication with the PT provider American Association of Bioanalysts (AAB) program representative; the laboratory failed to successfully participate in the testing of the specialty hematology for event 3 of 2020 and event 1 of 2021. Findings include: 1. Review of the CASPER Report 0155D, generated on 05-03-2021, revealed the initial unsuccessful performance for the specialty of hematology.
HEMATOLOGY - EVENT 3, 2020 0% Unsatisfactory HEMATOLOGY - EVENT 1, 2021 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 05/06/2021 at 8:37 AM, confirmed the unsuccessful performance for the specialty of hematology for event 3 of 2020 and event 1 of 2021.