Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D2161589	**(X3) Date Survey Completed** 12/14/2022
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	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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with the American Association of Bioanalysts (AAB) PT program representative confirmed the laboratory's SUBSEQUENT unsuccessful PT performance for the specialty of hematology (See D2131) and the following hematology analytes: cell identification /white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets (See D2130) for three of three PT events in 2022 and two of three events in 2020 through 2021 (event 3 of 2021 and events 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with the American Association of Bioanalysts (AAB) PT program representative the laboratory failed to achieve satisfactory performance for the hematology analytes cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets for three of three consecutive PT events in 2022 and two of three events in 2020 and 2021 (event 3 of 2020 and event 1 of 2021) resulting in subsequent unsuccessful PT performance. Findings include: 1. Review of the CASPER Report 0155D, generated on 12-01-2022, and the AAB PT records the laboratory received the following unsatisfactory analyte scores: Cell Identification /White Blood Cell Differential EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory Red Blood Cells EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory Hematocrit EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory Hemoglobin EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory White Blood Cells EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory Platelets EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 12-02-2022 at 3:24 PM, 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 3 of 2020, event 1 of 2021, and events 1, 2, and 3 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with the American Association of Bioanalysts (AAB) PT program representative the

	laboratory failed to achieve satisfactory performance for the specialty of hematology for three of three PT events in 2022 and two of three PT events from 2020 through 2021 (event 3 of 2020 and event 1 of 2021) resulting in subsequent unsuccessful PT performance for the overall specialty of hematology. Findings include: 1. Review of the CASPER Report 0155D, generated on 12-02-2022, and AAB PT records, the laboratory received the following unsatisfactory scores for the specialty of hematology. HEMATOLOGY EVENT 3, 2020 0% Unsatisfactory EVENT 1, 2021 0% Unsatisfactory EVENT 1, 2022 0% Unsatisfactory EVENT 2, 2022 0% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory 2. A phone interview with the (AAB) PT representative on 12-02-2022 at 3:24 PM, confirmed the subsequent unsuccessful performance for the overall specialty of hematology for event 3 of 2020, event 1 of 2021, and events 1, 2, and 3 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with an AAB PT program representative the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialty of hematology (see D6016) resulting in the laboratory's subsequent unsuccessful PT performance for the overall specialty of hematology and the following hematology analytes: cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets.
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 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with an AAB PT program representative the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialty of hematology (see D2130 and D2131) resulting in the laboratory's subsequent unsuccessful PT performance for the overall specialty of hematology and the following hematology analytes: cell identification/white blood cell differential, red blood cells, hematocrit, hemoglobin, white blood cells, and platelets.