Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D1065537	(X3) Date Survey Completed 05/04/2020
Name of Provider or Supplier Lovelace Regional Hospital - Roswell	**Street Address, City, State** 117 East 19th St, Roswell, NM	
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	During a proficiency desk review on 05/04/2020, the laboratory was found out of compliance with the following condition: 42 CFR Part 493.803 Proficiency Testing, Successful Participation
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: Based on the review of shipping calendars from the proficiency agency websites, emails from laboratory representatives, proficiency test reports from the Centers for Medicare & Medicaid Services (CMS) proficiency database, the laboratory failed to notify the New Mexico Department of Health of the intent to enroll with a new proficiency testing agency for the calendar year 2020. Findings are: A. Review of the Centers for Medicare & Medicaid CASPER report 155, Proficiency Test scores dated 05/01/2020, revealed the laboratory enrolled in proficiency testing with 2 different agencies, AAB and CAP for 2020 using the same CLIA number. The laboratory received a score of 0% for all analytes from AAB and 100% from CAP. B. Review of the shipping calendar for both proficiency agencies and emails from the laboratory revealed: 1. AAB samples for the 1st event of 2020 were shipped on 02/04/2020. 2. CAP samples for the 1st event of 2020 The Coagulation module, including Fibrinogen, was shipped on 01/27/2020. The Aqueous Blood Gas module was shipped on 02/24/2020. 3. On 02/12/2020, the laboratory sent an application for the new laboratory operator via email to the New Mexico Department of Health but did not include notification of the change to a new proficiency testing agency.
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 reports from the Centers for Medicare & Medicaid Services (CMS) proficiency database, the laboratory failed to successfully participate in proficiency testing for PCO2 and Fibrinogen. Findings are: A. Review of the Centers for Medicare & Medicaid CASPER Report 155, Proficiency Test scores dated 05/01 /2020, revealed the laboratory failed 2 of 3 test events for the analyte PCO2. See D2096 2nd event 2019 = 60% 1st event 2020 = 0% B. Review of the Centers for Medicare & Medicaid CASPER Report 155, Proficiency Test scores dated 05/01/2020 revealed the laboratory failed 2 out of 3 test events for the analyte Fibrinogen. See D2130 2nd event 2019 = 40% 1st event 2020 = 0%
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 the review of reports from the Centers for Medicare & Medicaid Services (CMS) proficiency database, the laboratory failed to receive passing scores for the analyte PCO2 for 2 of 3 test events in 2019 and 2020. Findings are: Review of the Centers for Medicare & Medicaid CASPER Report 155, Proficiency Test scores dated 05/01/2020 revealed: The laboratory failed 2 of 3 test events for the analyte PCO2 with the proficiency testing agency AAB. 2nd event 2019 = 60% 1st event 2020 = 0%
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 the review of proficiency test reports from the Centers for Medicare & Medicaid Services (CMS) proficiency database, the laboratory failed to successfully participate in proficiency for the analyte PCO2 for 2 of 3 test events in 2019 and 2020. Findings are: A. Review of the Centers for Medicare & Medicaid CASPER Report 155, Proficiency Test scores dated 05/01/2020 revealed: The laboratory failed 2 of 3 test events for the analyte PCO2 with the proficiency testing agency AAB. 2nd event 2019 = 60% 1st event 2020 = 0% B. Review of the Centers for Medicare & Medicaid CASPER Report 157 Excused Nonparticipation Report dated 04/27/2020, revealed no record that the laboratory had requested excused nonparticipation status for the 1st event of 2020 from the proficiency agency AAB.
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 the review of reports from the Centers for Medicare & Medicaid Services (CMS) proficiency database, the laboratory failed to receive passing scores for the analyte Fibrinogen for 2 of 3 test events in 2019 and 2020. Findings are: Review of the Centers for Medicare & Medicaid CASPER Report 155, Proficiency Test Scores dated 05/01/2020, revealed the laboratory failed 2 of 3 test events for the analyte Fibrinogen with the proficiency testing agency AAB. 2nd event 2019 = 40% 1st event 2020 = 0%
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 the review of reports from the Centers for Medicare & Medicaid Services (CMS) proficiency database, the laboratory failed to successfully participate in proficiency testing for the analyte Fibrinogen for 2 of 3 test events in 2019 and 2020. Findings are: A. Review of the Centers for Medicare & Medicaid CASPER Report 155, Proficiency Test Scores dated 05/01/2020, revealed the laboratory failed 2 of 3 test events for the analyte Fibrinogen with the proficiency testing agency AAB. 2nd event 2019 = 40% 1st event 2020 = 0% B. Review of the Centers for Medicare & Medicaid CASPER Report 157 Excused Nonparticipation Report dated 04/27/2020, revealed no record that the laboratory had requested excused nonparticipation status for the 1st event of 2020 from the proficiency agency AAB.