| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 32D0536885 | 09/23/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Colfax General Laboratory | 615 Prospect Ave, Springer, 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 |
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| **D0000** | During a recertification survey completed on 09/23/2020 for 42 CFR part 493 Laboratory requirements, the facility was found out of compliance with the following condition: 42 CFR PART 493.1415 Clinical Consultant Moderate Complexity Testing |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of patient test logs, manufacturer instructions, Technical Consultant Reviews, and interviews with laboratory staff, the laboratory failed to follow the manufacturer's instructions to discontinue the use of recalled Prothrombin Time/INR (International Normalized Ratio - a calculated value used to standardize reporting of different test methods) test strips. 41 patients (COAG 1 - COAG 41) were tested August 2018-June 2019 using the recalled strips for a total of 260 tests. Findings are: A. Review of a Roche product recall notice dated 10/31/2018, published on the FDA (Food & Drug Administration) website, indicated: 1. The company had recalled CoaguChek XS PT Test Strips used for monitoring patients on oral anticoagulant therapy due to "inaccurately high INR test results." 2. "Patients taking warfarin (an anticoagulant or blood thinner that reduces the formation of blood clots) who receive inaccurate INR results above their target therapeutic range may be at risk for inappropriate therapeutic measures such as a warfarin dose reduction, interruption of warfarin use, or administration of vitamin K." 3. The updated recall notice included a series of lot numbers that were affected by the recall as well as the original notification date of the recall, 09/12/2018. B. Review of the laboratory records revealed 2 copies of recall notices. 1. Recall #1, dated 11/5/2018 and reviewed at the laboratory, indicated: a. It was an update to the notice sent on 09/12/2018. b. The |

affected lot numbers affected by the recall fell within a range, 27216700 through 33449899. Individual lot numbers were not listed on this copy of the recall notice nor was there any documentation indicating the laboratory had reviewed it. 2. Partial images of Recall #2, provided by the Laboratory Supervisor via text message on 09/17/2020 and signed by him on 11/09/2018, also indicated the range of lot numbers, 27216700 through 33449899. This copy of the notice also listed specific lot numbers. An undated sticky note on the notice indicated, "Lab does not have any of these lot #'s." C. Review of the Roche website regarding the 2018 recall revealed, "Roche Diagnostics issued an Urgent Medical Device Correction (UMDC) in September 2018 instructing patients and healthcare practitioners to confirm any CoaguChek test results above an INR of 4.5 with another testing method. This UMDC was distributed to CoaguChek distributors, customers, healthcare professionals and patients via mail." D. Review of the Technical Consultant's quarterly reviews for the last six months of 2018 revealed no documentation indicating the laboratory had received the recall notices and performed any corrective actions. 1. August, September, and October 2018 report for an on-site visit dated October 13, 2018 - Section heading Reagent Bulletins, the Technical Consultant wrote, "No regent bulletins or product recalls were received for the 3rd QTR of 2018." 2. October, November, and December 2018 for an on-site visit dated January 18, 2019 - Section heading Reagent Bulletins, the Technical Consultant wrote, "No regent bulletins or product recalls were received for the 4th QTR of 2018." D. During interview on 09/16/2020 at 09:16 am, the Laboratory Director (also serving as the Technical Consultant) stated she was not aware of the recall of the CoaguChek XS PT Test Strips. E. Review of the CoaguChek patient test logs revealed the laboratory used Lot 28632412 (listed on the recall dated 11/08/2019 and from the FDA notice dated 10/31/2018) from 08/21/2018 - 06/28/2019 for patient testing. There was no documentation indicating the laboratory discontinued the use of the strips or used an alternate method to confirm INR results > 4.5. 1. The following patients (COAG 2, COAG 3, COAG 8, COAG 15, COAG 20, COAG 22, COAG 26 and COAG 27) had INRs >4.5 using the recalled test strips. COAG 2 on 1/31/2019 = 6.5/6.5 COAG 3 on 3/29/2019 = 5.9/5.8 COAG 8 on 09/26/2018 = 5.6 and 10/24/18 = 4.1/3.9 COAG 15 on 11/09/2018 = 7.3/7.8 COAG 20 on 04/29/2019 = 7.2/7.5 and 5/31/19 = 5.5/5.6 COAG 22 on 05/02/2019 = 4.8/4.8 COAG 26 on 12/14/2018 = 4.5/4.2 COAG 27 on 06/28/2018 = 4.8/4.9 and 05/31/2019 = 5.5/5.6 2. The recalled test strips were used repeatedly for the following patients for a total of 260 tests reported: COAG 1 6 tests 08/21/2018, 08/29/2018, 09/07/2018, 02/05/2019, 04/02/2019, and 06/18/2019 COAG 2 5 tests 12/10/2018, 12/19/2018, 01/03/2019, 01/17/2019, and 01/31/2019 COAG 3 43 tests 08/24/2018, 08/31/2018, 09/07/2018, 09/14/2018, 09/28/2018, 10/02/2018, 10/05/2018, 10/12/2018, 10/19/2018, 10/26/2018, 11/02/2018, 11/09/2018, 11/16/2018, 11/30/2018, 12/07/2018, 12/14/2018, 12/21/2018, 01/04/2019, 01/11/2019, 01/18/2019, 01/25/2019, 02/15/2019, 02/22/2019, 03/01/2019, 03/08/2019, 03/15/2019, 03/22/2019, 03/29/2019, 04/02/2019, 04/05/2019, 04/12/2019, 04/19/2019, 04/23/2019, 04/26/2019, 05/03/2019, 05/10/2019, 05/17/2019, 05/24/2019, 05/31/2019, 06/07/2019, 06/14/2019, 06/21/2019, and 06/28/2019 COAG 4 40 tests 08/27/2018, 09/04/2018, 09/10/2018, 09/17/2018, 09/24/2018, 10/01/2018, 10/10/2018, 10/16/2018, 10/22/2018, 11/05/2018, 11/13/2018, 11/19/2018, 12/12/2018, 12/18/2018, 12/28/2018, 01/02/2019, 01/08/2019, 01/14/2019, 01/23/2019, 01/28/2019, 02/04/2019 02/11/2019, 02/19/2019, 02/25/2019, 03/06/2019, 03/11/2019, 03/18/2019, 04/01/2019, 04/08/2019, 04/15/2019, 04/22/2019, 04/29/2019, 05/06/2019, 05/13/2019, 05/20/2019, 05/28/2019, 06/05/2019, 06/10/2019, 06/17/2019,and 06/24/2019 COAG 5 12 tests 08/27/2018, 10/12/2018, 11/20/2018, 11/30/2018, 12/28/2018, 02/08/2019, 03/15/2019, 04/12/2019, 05/10/2019, 05/24/2019, 06/21/2019, and 06/27/2019 COAG 6 10 tests 08/27/2018, 09/10/2018, 09/19/2018, 10/11/2018, 12/10/2018, 01/09/2019, 02/11/2019, 03/11/2019, 04/10/2019, and 05/10/2019 COAG 7 2 tests 08/27

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| | /2018 and 09/06/2018 COAG 8 40 tests 08/29/2018, 09/05/2018, 09/13/2018, 09/19 /2018, 09/26/2018, 09/28/2018, 10/03/2018, 10/09/2018, 10/17/2018, 10/24/2018, 10 /31/2018, 11/07/2018, 11/14/2018, 11/21/2018, 11/28/2018, 12/12/2018, 12/19/2018, 12/26/2018, 01/02/2019, 01/09/2019, 01/16/2019 01/23/2019, 02/13/2019, 02/20 /2019, 02/27/2019, 03/06/2019, 03/13/2019, 03/20/2019 03/27/2019, 04/03/2019, 04 /10/2019, 04/18/2019, 04/24/2019, 05/01/2019,05/08/2019, 05/22/2019, 06/05/2019, 06/12/2019, 06/20/2019, and 06/26/2019 COAG 10 1 test 08/31/2018 COAG 11 1 test 09/04/2018 COAG 12 2 tests 09/04/2018, and 06/18/2019 COAG 13 11 tests 09/04 /2018, 09/18/2018, 10/02/2018, 10/16/2018, 10/30/2018, 11/20/2018, 12/11/2018, 01 /04/2019, 01/18/2019, 03/08/2019, and 04/16/2019 COAG 14 3 tests 09/04/2018, 11 /06/2018, and 01/25/2019 COAG 15 12 tests 09/07/2018, 10/02/2018, 10/23/2018, 11 /09/2018, 11/27/2018, 12/18/2018, 01/08/2019, 01/18/2019, 01/22/2019, 02/22/2019, 03/26/2019, and 04/26/2019 COAG 16 7 tests 09/10/2018, 11/19/2018, 12/10/2018, 01 /14/2019, 02/11/2019, 03/11/2019, and 06/10/2019 COAG 17 2 tests 09/13/2018 and 06/13/2019 COAG 18 8 tests 09/20/2018, 10/03/2018, 10/22/2018, 12/06/2018, 01/09 /2019, 03/20/2019, 04/23/2019, and 06/18/2019 COAG 19 7 tests 09/20/2018, 10/22 /2018, 12/06/2018, 01/09/2019, 03/20/2019, 04/23/2019, and 06/18/2019 COAG 20 7 tests 09/27/2018, 10/25/2018, 01/04/2019, 01/24/2019, 03/28/2019, 04/29/2019, and 05/03/2019 COAG 21 3 tests 10/01/2018, 11/26/2018, and 12/03/2018 COAG 22 6 tests 10/04/2018, 11/19/2018, 01/07/2019, 02/18/2019, 05/02/2019, and 06/12/2019 COAG 23 2 tests 10/04/2018 and 10/31/2018 COAG 24 1 test 10/05/2018 COAG 25 2 tests 12/07/2018 and 12/18/2018 COAG 26 1 test 12/14/2018 COAG 27 7 tests 12 /14/2018, 04/05/2019, 04/19/2019, 05/03/2019, 05/31/2019, 06/11/2019, and 06/28 /2019 COAG 28 1 test 12/21/2018 COAG 29 1 test 01/09/2019 COAG 30 3 tests 02 /22/2019, 04/12/2019, and 06/10/2019 COAG 31 1 test 02/27/2019 COAG 32 1 test 03 /01/2019 COAG 33 1 test 03/06/2019 COAG 34 4 tests 03/12/2019, 03/20/2019, 06/21 /2019, and 06/28/2019 COAG 35 1 test 03/14/2019 COAG 36 2 tests 03/19/2019 and 05/07/2019 COAG 37 1 test 03/20/2019 COAG 38 1 test 05/10/2019 COAG 39 1 test 06/04/2019 COAG 40 1 test 06/07/2019 COAG 41 1 test 06/18/2019 |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of quality control records and interview with the Laboratory Supervisor, the laboratory failed to maintain copies of all manufacturer instructions for at least 2 years. Findings are: A. Review of 2018-2020 quality control records revealed no copies of the Roche quality control package inserts that provide specific information about the acceptable ranges and handling instructions of the control material. B. When asked for the current and past quality control package inserts on 09 /16/2020 at 10:00 am, the Laboratory Supervisor stated that the laboratory did not keep copies of the manufacturer's package inserts for reagents, quality control, and calibration materials. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed |

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| | following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the manufacturer's instructions for the chemistry analyzer and interview with the Laboratory Supervisor, the laboratory failed to upload the required software upgrade for the Cobas c111 chemistry analyzer which establishes and verifies test system performance. Findings are: 1. Review of the Cobas c111 (chemistry analyzer) Operator Manual revealed a mandatory Software Bulletin dated 02/20/2018, which stated "The upgrade to Cobas c111 analyzer software version 4.2.2.1730 is mandatory." 2. During interview on 09/15/2020 at 02:07 pm, the Laboratory Supervisor stated that the Field Technical Specialist said "the display was not compatible with the new version" and that he was unable to do the upgrade. The Laboratory Supervisor was unable to provide any written, supportive documentation from Field Technical Specialist regarding the software upgrade. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of 2020 quality control records, patient reports, laboratory policy, quality assessment reports from the Technical Consultant(also serving as Laboratory Director) and interviews with laboratory staff, the laboratory failed to perform and document the verification of the Roche c111 quality control materials prior to use. 26 patients (CHPT#3-CHPT#28) were tested 05/19/2020 - 06/07/2020. Findings are: A. Review of the Roche c111 quality control comparison study (or lot-to-lot) performed 05/18/2020 - 05/19/2020 revealed no documentation of the criteria used to review and approve the use of the new lot of quality control materials when the Technical Consultant reviewed the data on 06/08/2020. B. Review of the Instrument printouts revealed the laboratory ran the new lot of controls 3 times on a single date (05/19 /2020) and the data compared to the old lot of controls run on 05/18/2020. C. Review of the laboratory's quality control ranges revised on 05/29/2020 revealed no documentation indicating approval by the Technical Consultant. Quality Control materials in use: PNU Lot 42392601 expiration date 02/28/2022 PPU Lot 30564005 expiration date 05/31/2021 Precicontrol multi 2 Lot 32434804 expiration date 04/30 /2021 Precicontrol multi 1 Lot 32420904 expiration date 08/31/2021 Ammonia/N (used for Carbon Dioxide) Lot 42750801 expiration date 10/31/2020 Ammonia/P |

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| | (used for Carbon Dioxide) Lot 42750901 expiration date 10/31/2020 D. Review of the laboratory's quality control policy dated 10/08/2018 indicated: "New Control Lot # Comparison: Target means, and ranges established by manufacturer for quantitative tests are used as a guide for performance for any new lot. [Name of Lab] lab values will be within the established manufacturers ranges. ... Standard deviations are calculated with the initial evaluation. Old lot #'s and new lot #'s are performed and compared. Historically established target SDs (Standard Deviation) may be used for new control lots if the mean of the new lot is similar to the mean of the current lot." E. Review of the Technical Consultant's quality assessment report dated 07/20/2020 for April, May, and June 2020 revealed no documentation of her review and approval of the new quality control ranges implemented on 05/19/2020. F. Review of patient test records revealed 26 patients (CHPT#3-CHPT#28) were tested 05/19/2020 - 06/07 /2020, prior to the review of the new quality control ranges by the Technical Consultant on 06/08/2020. 05/19/2020 2 patients; CHPT#27 and CHPT#28 05/20 /2020 1 patient; CHPT#26 05/27/2020 1 patient; CHPT#24 05/29/2020 4 patients; CHPT#21, CHPT#22, CHPT#23, and CHPT#25 06/01/2020 6 patients; CHPT#15, CHPT#16, CHPT#17, CHPT#18, CHPT#19, and CHPT#20 06/03/2020 8 patients; CHPT#6, CHPT#7, CHPT#8, CHPT#9, CHPT#11, CHPT#12, CHPT#13, and CHPT#14 06/04/2020 2 patients; CHPT#5 and CHPT#10 06/05/2020 2 patients; CHPT#3 and CHPT#4 G. During interview on 09/16/2020 at 09:00 am, the Laboratory Supervisor stated the Technical Consultant/Laboratory Director had not reviewed the lot-to-lot comparison and confirmed the laboratory had not followed the laboratory's quality control policy. H. During interview by phone on 09/16/2020 at 9: 20 am, the Technical Consultant/Laboratory Director stated she discussed the quality control lot-to-lot comparison study with the Laboratory Supervisor by phone. 43577 |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of patient test logs,patient reports, manufacturer instructions, Cobas c111 Operator Manual, 2020 quality control records, laboratory policy, quality assessment reports from the Technical Consultant (also serving as Laboratory Director) and interviews with laboratory staff, the laboratory failed to have an effective quality assessment program. Findings are: A. The laboratory failed to follow the manufacturer's instructions to discontinue the use of recalled Prothrombin Time /INR (International Normalized Ratio - a calculated value used to standardize reporting of different test methods) test strips. 41 patients (COAG 1 - COAG 41) were tested August 2018-June 2019 using the recalled strips for a total of 260 tests. . See D1001 B. The laboratory failed to upload a required software upgrade to the Cobas c111 analyzer which establishes and verifies test system performance. See D5411 C. The laboratory failed to perform and document the verification of the Roche c111 quality control materials prior to use. 26 patients (CHPT#3-CHPT#28) were tested 05 /19/2020 - 06/07/2020, See D5469 |
| **D5813** | TEST REPORT |

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| | CFR(s): 493.1291(g)<br><br>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of patient records selected from the laboratory's Critical List log, and interview with Laboratory Supervisor, the laboratory failed to copy the documented notification call for eight (Pt#1-Pt#8) of eight (Pt#1-Pt#8) critical and panic values from the hard copy to the permanent electronic record. Findings are: A. Review of electronic records for Pt#1, Pt#2, and Pt#6, revealed no documentation of notification of critical values to the authorized individual or entity, from the hard copy to the permanent electronic record in the Schuylab LIS software system. B. Review of the hard copies of five patient records (Pt#3, Pt#4, Pt#5, Pt#7, Pt#8), which were tested on the Coagucheck XS (POC PT analyzer used for monitoring patients on anticoagulant therapy), which is not interfaced with the Schuylab LIS software system, revealed incomplete documentation of notification regarding critical or panic values. a. Pt#3, Pt#4, Pt#7 contained "called to" comments but no date of call, no time of call, no test result, and no documentation in regards to who called the result. b. Pt#5, and Pt#8 contained "called to" comments along with the date of call, but no time of call, no test result, and no documentation in regards to who called the result. C. During interview on 09/16/2020 at 11:05 am, the Laboratory Supervisor stated that there was no way to type in and copy the "called to" comment from the hard copies of all patient reports to the Schuylab LIS system, regardless if the instruments are interfaced with LIS or not. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of 2020 quality control records, laboratory policy, and quality assessment reports from the Laboratory Director/Technical Consultant and interviews with laboratory staff, the Laboratory Director failed to ensure quality control policies were followed and documented by laboratory staff. Findings are: The laboratory failed to perform and document the verification of the Roche c111 quality control materials prior to use. See D5469 |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are |

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| | maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of 2020 quality control records, laboratory policy, quality assessment reports from the Laboratory Director/Technical Consultant and interviews with laboratory staff, the Technical Consultant failed to ensure quality control policies were followed and documented by laboratory staff. Findings are: The laboratory failed to perform and document the verification of the Roche c111 quality control materials prior to use. See D5469 |
| **D6056** | CLINICAL CONSULTANT<br>CFR(s): 493.1415<br><br>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.<br><br>This CONDITION is not met as evidenced by:<br>Based on the review of the CMS (Centers for Medicare & Medicaid Services) Form 209, Laboratory Personnel, and personnel records, the laboratory failed to have a qualified Clinical Consultant. Findings are: The designated Clinical Consultant did not meet the requirements for Clinical Consultant. See D6057 |
| **D6057** | CLINICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1417<br><br>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the CMS (Centers for Medicare & Medicaid Services) Form 209, Laboratory Personnel, and personnel records the laboratory failed to have a qualified Clinical Consultant. Findings are: A. Review of CMS form 209, Laboratory Personnel report, sent in as part of survey packet and signed by current Laboratory Director on 09-11-20, identified CC#1 as the Clinical Consultant. B. Review of the personnel records for CC#1, revealed that CC#1 was a Certified Nurse Practitioner not a medical doctor, doctor of osteopathy or podiatry. |