

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D1003498	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier New Mexico Primary Care Laboratory	Street Address, City, State 179 Howard Place, Las Cruces, 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 an initial certification survey completed on 03/27/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1409 Technical Consultant, Moderate Complexity
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of testing supplies, review of manufacturer instructions, quality control logs and interviews with laboratory staff, the laboratory failed to follow the manufacturer's instructions for storage, handling, and discarding supplies that are expired. Findings are: A. Observation of testing supplies located in the waived testing room on 03/27/19 at 08:00 am revealed the following expired reagents/supplies: 1. Quantisal Oral Fluid collection device, lot EK15484 expiration date February 2019, 7 collection devices 2. MCC KOH 10% solution, lot 5773-02 expired 04/2018 3. Healthlink KOH 10% solution lot 1508407, expiration date 03/24/2016 4. Consult Occult Blood Developer, lot 2-16-551622, expiration date 11/2018 B. Observation of testing supplies located in the waived testing room on 03/27/19 at 08:00 am revealed the laboratory failed to ensure that all reagents belonging to a test kit were maintained with documentation of manufacturer issued lot number and expiration date of the kit and ensure that reagents from one kit were not used with another kit. 1. The reagents and strips for the Consult Strep A test kit were removed from the original box and placed in another container. There was no documentation of the manufacturer's lot number and expiration date of the entire kit which can differ from the expiration dates on the individual reagents. Reagent 1, lot 18030263, expiration date 06/20/2020 Reagent 2, lot 18040078, expiration date 07/10/2020 Dipsticks, lot STA8050012,</p>

expiration date 04/30/2020 C. Observation of testing supplies located in the waived testing room on 03/27/19 at 08:00 am revealed the laboratory failed to document revised expiration dates for: Alere Afinion HbA1c, Lot 10198559 expiration date 09/2020; 8 cartridges 1. The laboratory stored the supplies for the Alere Afinion HbA1c test system on the center cart along one wall. The test cartridges for hemoglobin A1C were at room temperature. The acceptable storage temperature on the label indicated that the cartridges should be stored at 2-8 degrees Celsius. 2. Review of the manufacturer's instructions for the Alere HbA1c cartridges indicated that the cartridges may be stored at room temperature (15-25 degrees Celsius) for up to 90 days. There was no documentation on the cartridge packaging to indicate the date the cartridges were removed from the refrigerator nor was there documentation of a revised expiration date. 3. During interview on 03/27/19 at 8:30 am, Staff #2 stated that she did not know when the HbA1c cartridges were taken out of the refrigerator. 4. Review of the quality control log indicated that this lot of cartridges was tested on 03/12/19. D. Observation of the waived testing room on 03/27/19 at 08:30 am revealed no evidence of a thermometer for monitoring the room temperature. 1. During interview on 03/27/19 at :08:30 am, Staff #2 confirmed the laboratory did not monitor the temperature of the waived testing room.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed 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.

This STANDARD is not met as evidenced by:
 Based on the review of manufacturer instructions, laboratory policy, patient test reports and interview with the testing person, the laboratory failed to follow the manufacturer's instructions for the Horiba Micros 60 hematology analyzer and perform blood smear reviews when the SCH flag is present. Findings are: A. Review of the instructions for the Horiba Micros 60 hematology analyzer revealed that the presence of "SCH" flag on printouts indicated "excessive cell number between 18-25 fL (femtoliters), suspect presence of schizocytes (fragments of red blood cells) or platelet aggregates (clumps). Verify platelet on a stained blood smear." B. Review of 11 CBC (Complete Blood Counts) reports revealed 1 patient, #3628, had a "SCH" on the original report and on the repeat run. There was no indication that a blood smear was reviewed or sent to a reference laboratory for review. C. During interview on 03/27/19 at 1:55 pm, the testing person stated that he repeats the run and if the SCH flag remains, he shows the printout to the provider to decide if it needs to be sent out. D. Review of the final report for Patient #3628 revealed the comment "SCH flag, specimen rerun, flag remains. Discussed w/provider - no manual review." E. Review of laboratory policy, "Review of Hematology Results from 8/4/18 through 10/12/18" signed by the testing person on 10/15/18, indicated the following regarding the "SCH" flag: "Specimens with Morphology flags SCH indicates excessive cell number between 18-25 fL, suspect presence of schizocytes or platelet aggregates. Verify platelet on a stained blood smear. Sample should be placed on rocker for 15 minutes and rerun. If flag is not resolved after rerun - specimen must be sent for manual review."

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on the review of manufacturer instructions, instrument printouts (tapes), and interview with the testing person, the laboratory failed to perform calibration procedures according to manufacturer instructions. 100 patients were tested using expired calibration curves for Testosterone, Thyroxine, Estradiol, Vitamin B12, and Prostate Specific Antigen. Findings are: The laboratory failed to ensure calibration curves were not expired prior to performing and reporting patient testing. A. Review of the manufacturer's instructions revealed that the presence of a "CV" flag on the instrument tape meant "The period of validity of the calibration curve has been exceeded. Consequently the concentration will be calculated using a calibration curve whose period of validity has been exceeded." B. Review of the TOSOH AIA 900 analyzer printouts for November 2018 and February 2019 revealed the laboratory reported patients using an expired calibration curve. 1. Vitamin B 12 Patient testing was performed using an expired calibration curve 2 of 9 test days in November 2018. a. 11/16/18 - 10 patients were tested and results reported with a "CV" flag. Patient #2104 at 18:20 pm. #2129 at 18:22 and 19:30 #2164 at 18:28 #2154 at 18:33 #2165 at 18:38 #2167 at 18:40 #2158 at 18:41 #2136 at 19:16 and 20:24 #2091 at 19:18 #2104 at 19:31 b. 11/21/18 - 7 patients were tested and results reported with a "CV" flag. Patient #2224 at 15:21 #2228 at 15:23 #2221 at 15:28 #2223 at 15:32 #2179 at 15:35 #1880 at 15:50 #2216 at 17:02 2. T4 (Thyroxine) Patient testing was performed using an expired calibration curve 6 of 20 test days in February 2019. a. 02/07/19 - 3 patients were tested and results reported with a "CV" flag. Patient #3460 at 13:02 pm #3459 at 13:07 #3521 at 16:01 b. 02/12/19 - 3 patients were tested and results reported with a "CV" flag. Patient #3510 at 13:23 pm #3622 at 14:04 #3638 at 16:06 c. 02/14/19 - 5 patients were tested and results reported with a "CV" flag. Patient #3696 at 14:01 pm #3674 at 14:47 #3715 at 16:27 #3716 at 16:33 #3716 at 16:33 d. 02/18/19 - 2 patients were tested and results reported with a "CV" flag. Patient #3738 at 17:20 pm #3760 at 17:58 e. 02/20/19 - 4 patients were tested and results reported with a "CV" flag. Patient #3834 at 14:27 pm #3821 at 14:34 #3837 at 16:32 #3824 at 17:35 f. 02/25/19 - 4 patients were tested and reported with a "CV" flag. Patient #3892 at 18:01 pm #3861 at 18:41 #3860 at 18:45 #3925 at 21:16 3. PA (Prostate Specific Antigen) Patient testing was performed using an expired calibration curve 2 of 7 test days in February 2019. a. 02/07/19 - 9 patients were tested and results reported with a "CV" flag. Patient #3546 at 12:17 pm #3552 at 12:52 #3524 at 12:54 #3522 at 12:52 #3524 at 12:54 #3514 at 12:58 #3513 at 13:00 #3469 at 13:06 #3459 at 13:07 b. 02/12/19 - 7 patients were tested and results reported with a "CV" flag. Calibration was not performed until 02/15/19 at 09:59 am. Patient #3577 at 11:50 am #3568 at 11:56 #3570 at 12:01 pm #3569 at 12:20 #3567 at 12:20 #3630 at 14:07 #3636 at 14:46 4. Testosterone Patient testing was performed using an expired calibration curve 5 of 6

test days in February 2019. a. 02/12/19 - 5 patients were tested and results reported with a "CV" flag. Patient #3521 at 12:16 pm #3622 at 14:04 #3638 at 16:06 #3639 at 16:12 #3632 at 17:08 b. 02/14/19 - 3 patients were tested and results reported with a "CV" flag. Patient #3674 at 14:47 pm #3715 at 16:25 #3716 at 16:33 and 17:06 c. 02/18/19 - 2 patients were tested and results reported with a "CV" flag. Patient #3738 at 17:20 pm #3760 at 17:58 d. 02/22/18 - 9 patients were tested and results reported with a "CV" flag. Patient #3837 at 13:03 pm and again at 13:25 #3834 at #13:43 #3824 at 13:45 #3811 at 13:45 #3792 at 13:46 #3860 at 13:49 #3861 at 13:50 #3891 at 14:42 #3892 at 14:43 e. 02/25/19 - 2 patients were tested and results reported with a "CV" flag. Patient # 3920 at 20:07 pm #3925 at 21:16 5. Estradiol Patient testing was performed using an expired calibration curve 5 of 6 test days in February 2019. a. 02/12/19 - 5 patients were tested and results reported with a "CV" flag. Patient #3521 at 12:16 pm #3620 at 15:45 #3638 at 16:06 #3622 at 14:04 #3639 at 16:12 b. 02/14/19 - 7 patients were tested and results reported with a "CV" flag. Patient #3646 at 12:54 pm #3696 at 14:27 #3678 at 14:43 #3674 at 14:46 #3709 at 14:59 #3715 at 16:25 #3716 at 16:33 c. 02/18/19 - 3 patients were tested and results reported with a "CV" flag. Patient #3738 at 17:20 pm #3728 at 17:23 #3760 at 18:30 d. 02/20/19 - 7 patients were tested and results reported with a "CV" flag. Patient #3791 at 13:48 pm #3724 at 13:49 #3792 at 13:58 #3777 at 14:18 #3834 at 14:28 #3824 at 16:22 #3837 at 16:32 e. 02/25/19 - 7 patients were tested and results reported with a "CV" flag. Patient #3892 at 18:01 pm #3846 at 18:27 #3861 at 18:41 #3860 at 18:48 #3891 at 18:49 #3925 at 21:18 #3926 at 21:21 C. During interview on 03/27/19 at 04:20 pm, the testing person stated that he did not know what the "CV" flag meant on the printouts.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(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.

This STANDARD is not met as evidenced by:

Based on the review of manufacturer instructions, instrument printouts (tapes), and interview with the laboratory staff, the laboratory failed to have a quality assurance plan that included periodic review of instrument printouts. Findings are: A. The laboratory failed to perform calibration procedures according to manufacturer instructions. 100 patients were tested using expired calibration curves for Testosterone, Thyroxine, Estradiol, Vitamin B12, and Prostate Specific Antigen. See D5439 B. During interview on 03/27/19 at 04:00 pm, the technical consultant confirmed that she did not review the TOSOH AIA 900 instrument tapes as part of her monthly reviews.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on the review of personnel training/competency, manufacturer instructions, monthly reviews and interviews with laboratory staff, the technical consultant failed to provide effective technical oversight of the laboratory. Findings are: A. The technical consultant failed to ensure that the performed corrective actions in response to instrument error flags or codes on the TOSOH 900 immunoassay analyzer and the Horiba Micros 60 hematology analyzer. See D6042 B. The technical consultant failed to include review of instrument printouts as part of the competency assessment. See D6049

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(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 maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on the review of manufacturer instructions, instrument printouts and tapes, and interview with the laboratory staff, the technical consultant failed to ensure that the laboratory followed manufacturer's instructions in response to instrument error flags or codes on the TOSOH 900 immunoassay analyzer and the Horiba Micros 60 hematology analyzer. Findings are: A. The laboratory failed to perform calibration procedures according to manufacturer instructions. 100 patients were tested using expired calibration curves for Testosterone, Thyroxine, Estradiol, Vitamin B12, and Prostate Specific Antigen. See D5439 B. The laboratory failed to follow the manufacturer's instructions for the Horiba Micros 60 hematology analyzer and perform blood smear reviews when the SCH flag is present. See D5411

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on the review of personnel competency, manufacturer instructions, monthly reviews and interviews with laboratory staff, the technical consultant failed to include review of instrument printouts as part of the competency assessment. Findings are: A. The laboratory failed to follow the manufacturer's instructions for the Horiba Micros 60 hematology analyzer and perform blood smear reviews when the SCH flag is present. See D5411 B. The laboratory failed to perform calibration procedures according to manufacturer instructions. See D5437 C. Review of the competency assessment for the only testing person dated 01/03/19 had no reference to issues with calibrations or following protocols for the "SCH" flag. D. During interview on 03/27 /19 at 04:00 pm, the technical consultant confirmed that she did not review the TOSOH AIA 900 instrument tapes as part of her monthly reviews.