| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 32D1003242 | 12/04/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Srirengam Muralidhasa Md Llc | 1605 El Paseo Street, 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 |
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| **D0000** | During a recertification survey completed on 12/04/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.803 Proficiency Testing, Successful Participation |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on the review of 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, and laboratory proficiency testing records, the laboratory failed to successfully participate in proficiency testing for Chloride. The laboratory reported performing 3,026 Chloride tests in a 12 month period. Findings are: A. Review of CASPER Report 153 and 96 |

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| | from the CMS proficiency database revealed the laboratory received failing scores for the analyte Chloride for two (2) of three (3) test events in 2019. 1st event score = 20% 3rd event score = 60% B. Review of proficiency test records from the proficiency testing agency also indicated the laboratory received failing scores for the analyte Chloride for two (2) of three (3) test events in 2019. See D2087 and D2094 |
| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, and laboratory proficiency testing records, the laboratory failed achieve a proficiency test score of at least 80% for 2 of 3 test events in 2019 for the analyte Chloride. Findings are: A. Review of CASPER Report 153 and 96 from the CMS proficiency database revealed the laboratory received failing scores for the analyte Chloride for two (2) of three (3) test events in 2019. 1st event score = 20% 3rd event score = 60% B. Review of proficiency test records from the proficiency testing agency also indicated the laboratory received failing scores for the analyte Chloride for two (2) of three (3) test events in 2019. C. Review of the laboratory's proficiency test records confirmed these findings. |
| **D2094** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(e)<br><br>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of 2019 proficiency test records from the proficiency testing agency, Centers for Medicare & Medicaid Services (CMS) proficiency database, and laboratory proficiency testing records, the laboratory must undertake training and technical assistance for the unsuccessful participation in proficiency testing for Chloride. Findings are: A. Review of CASPER Report 153 and 96 from the CMS proficiency database revealed the laboratory received failing scores for the analyte Chloride for two (2) of three (3) test events in 2019. 1st event score = 20% 3rd event score = 60% B. Review of proficiency test records from the proficiency testing agency also indicated the laboratory received failing scores for the analyte Chloride for two (2) of three (3) test events in 2019. 1. 1st event results indicated that the SDI (Standard Deviation Index, a method of comparing one laboratory to other similar laboratories) for 4 of 5 results were higher (>2.0) than the peer group. 2. 3rd event results indicated the SDI for 2 of 5 test results were higher (>2.0) than the peer group. C. Review of the laboratory's proficiency test records and corrective actions indicated |

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| | the laboratory took the following actions: 1. 02/02/19 - 03/27/19 - "Reruns on failed analytes still out of range. [TP #1] stated frozen samples were discolored. New samples were borrowed from [another laboratory], chloride electrode changed (it was within specs for exp date - changed at October PM [Preventive Maintenance]). Borrowed samples in range. Self evaluation samples ordered... All self evaluation samples within acceptable ranges. 2. 10/10/19 - 12/02/19 - "Reruns performed on CL after instrument PM. Electrode changed during PM (Preventive Maintenance) but was not yet due for change. Will place label on front of analyzer with electrode expiration date. Will discuss issue with manufacturer. Repeats in range. Provider does not feel these value discrepancies are a clinically insignificant issue." |
| **D6043** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(5)<br><br>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of February 2019 and September 2019 quality control records, laboratory policies, quality assurance reviews and interviews with laboratory staff, the Technical Consultant failed to ensure all corrective actions were documented by testing personnel. Findings are: A. Review of quality control records revealed failed quality control results or instrument errors but no documentation of actions taken by testing personnel to resolve the problems. N Control Lot 1802701 P Control Lot 1800201 1. February 2019 Chloride, ISE Errors and out of range results. a. Quality Control [Level not identified on report] was run 12 times on 02/05/19; 08:51 am, 09: 56 am, 11:01 am, 11:14 am, 11:35 am, 11:50 am, 13:44 pm, 13:56 pm, 14:16 pm, 15: 01 pm, 15:04 pm and 15:27 pm. b. Quality Control [Level not identified on report] was run 11 times on 02/08/19; 08:33 am, 08:53 am, 13:15 pm, 13:18 pm, 13:22 pm, 13:26 pm, 13:28 pm, 13:34 pm, 15:15 pm, 15:21 pm, 15:39 pm, and 15:46 pm. c. Quality Control [Level not identified on report] was run 7 times on 02/11/19; 09:56 am, 15:56 pm, 15:58 pm, 16:17 pm, 16:22 pm, 16:26 pm, and 16:30 pm. d. Quality Control [Level not identified on report] was run 5 times on 02/19/19; 13:41 pm, 13:56 pm, 14:05 pm, 14:22 pm, and 14:55 pm. 2. February 2019 Sodium, ISE Errors a. P Control was run on 02/08/19 a total of 3 times to obtain an acceptable value; 08:33 am, 08/53 am, and 13:15 pm. b. P Control lot 1800201, was run on 02/19/19 a total of 5 times to obtain an acceptable value; 13:41 pm, 13:56 pm, 14:05 pm, 14:22 pm, and 14:55 pm. 3. February 2019 Potassium, ISE Errors a. Quality Control [lot not identified], was run 4 times on 02/08/19; 08:33 am, 08:53 am, 13:15 pm, and 13:18 pm. b. Quality Control [lot not identified], was run 5 times on 02/19/19; 13:41 pm, 13: 56 pm, 14:05 pm, 14:22 pm, and 14:55 pm. 4. September 2019 Alkaline Phosphatase, Abnormal a. Quality Control [Level not identified on report] was run on 09/05/19 a total of 7 times to obtain an acceptable value; 11:29 am, 12:42 pm, 13:51 pm, 14:04 pm, 14:58 pm, and 15:17 pm. b. Quality Control Level [Level not identified on report] was run on 09/06/19 a total of 11 times to obtain an acceptable value; 10:19 am, 10:45 am, 11:03 am, 11:27 am, 11:42, 11:55 am, 12:51 pm, 13:10 pm, 13:31 pm, 13:39 pm, and 13:47 pm. 5. September 2019 Chloride, ISE Errors a. Quality Control [Level not identified], was run 3 times on 09/05/19; 11:31 am, 12:42 pm, and 13:52 pm. 6. September 2019 Sodium, out of range results a. Quality Control [Level not identified], was run 3 times on 09/13/19; 09:04 am, 09:31 am, and 09:57 am. b. Quality Control [Level not identified], was run 3 times on 09/20/19; 10:43 am, 12:02 pm, and 12:27 |

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| | pm. c. Quality Control [Level not identified], was run 3 times on 09/24/19; 08:40 am, 10:00 am. and 09:24 am. B. Review of the laboratory's quality control policy dated 03 /30/2011 indicated the following: "Check for obvious errors. 1. Controls a. Placed in the wrong position on the analyzer. b. Short-sampled c. Control material not handled properly, i.e. not properly mixed, cap left off vial, sample left on analyzer too long. 2. Instrument a. Maintenance procedures not performed according to maintenance schedule. b. Defective parts - check syringes for leaks, probe for plugs, etc. If a control issue, repeat control testing. Use judgement as to whether a fresh set of controls should be opened and run. If an instrument issue - Try any or all of the following: 1. Perform necessary maintenance 2. Recalibrate analyte, if applicable 3. Verify that reagent is within stability dating 4. Repeat analysis on control material after troubleshooting measures have been applied and instrument function has been restored. Document out of range control values and document actions taken on the appropriate logs/reports." C. Review of the Quality Assurance Reviews dated 03/05 /19 and 10/11/19 revealed no documentation by the Technical Consultant that addressed the failure to document corrective actions taken for errors or quality control failures in February 2019 and September 2019. D. During interview on 12/03/19 at 10: 20 am, the Technical Consultant stated that TP #1 "occasionally" documents problems and troubleshooting steps. E. During interview on 12/03/19 at 10:25 am, Testing Person #1 stated that she repeats the quality control, calibrates, and calls technical support but does not document these steps in the computer. She also stated that the laboratory did not have paper logs to document corrective actions. F. Review of the laboratory's Quality Assurance Plan dated 02/20/18 indicated: "Quality Control is reviewed on a monthly basis by the Technical Consultant to detect any trends or shifts. Corrective Action Logs will be reviewed monthly to ensure appropriate corrective documentation is recorded." |