Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1003242	01/11/2018
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
D0000	The following deficiencies were cited as the result of a recertification survey completed on 01/11/2018 for 42 CFR part 493 Laboratory Requirements.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the review of 2016-2017 proficiency test records, personnel records and interviews with laboratory staff, the laboratory failed ensure that all testing personnel participated in proficiency testing. Findings are: 1. Review of 2016-2017 proficiency test records and personnel records revealed that 1 of 2 current testing personnel (TP) had not participated in proficiency testing since she was trained to use the Horiba Micros 60 hematology analyzer in June 2016. 2. During interview on 1/09/2018 at 11: 54 am, TP1 confirmed that TP2 used the analyzer to performed CBC (complete blood count) testing. 3. During interview on 1/09/2018 at 1:50 pm, TP2 stated that she had helped TP1 with one event (she did not specify which event) but there was no documentation in the records.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on the review of patient records, redraw/recollection records, quality assurance records, and interviews with laboratory staff, the laboratory failed to have an effective system to track, assess, and perform corrective actions for specimens that were mislabeled, ordered incorrectly, or required recollection. This failed practice could result in delayed or inaccurate test result reporting to the ordering providers. Findings are: 1. Review of the laboratory binder "Pt redraws and error correction forms" revealed that the laboratory had not used this system since June 2016. TP #1 (Testing person #1) confirmed during interview on 1/10/2018 at 8:15 am that the laboratory isn't using this system to document redraws. She also stated that the redraw information was documented in the patient's electronic medical record under telephone encounters but not documented elsewhere in the laboratory. a. Review of 44 telephone encounters (July 2016 - January 8, 2018) revealed no documentation of the original collection date for each sample, only the contact date and time. TP #1 wrote in the recollection information on the printouts because that information was not included in the telephone encounter. 16 of the 44 patients did not have the sample redrawn or recollected. 2. Record review of monthly quality assurance records revealed no instances of redraws performed by the laboratory December 2015-December 2017. 3. Review of the redraw binder indicated the following: a. 4 patient samples (P41, P49, P48, and P47) were either mislabeled or ordered under the wrong patient name. Sample P41 (complete blood count and lead level) was collected on 2/02/2016. The note indicates that it was "drawn under the wrong patient." The other patient was not identified. The patient was called on 3/07/2016 but no other documentation was on the form indicating the laboratory followed up on the error. Sample P49 (rapid strep test) was collected on 12/14/2015. The document indicated that the medical assistant mislabeled the throat swab with P42's name. There was no documentation that the swab was recollected. Sample P48 (rapid strep test) was collected on 2/26/2016. The document indicated that the throat swab was mislabeled with P44's name but there was no documentation that the swab was recollected. Sample P47 (chemistry and complete blood count) was ordered and reported on 4/22/2016 as belonging to P45. b. 6 patients needed redraws (P1-P7) in December 2015 because the laboratory failed to put the test requests on the correct worklist. Sample P1, originally collected on 12/04/2015, was not redrawn until 4/01/2016 almost 4 months later. The laboratory did not call the patient until 12/29/15 for the redraw. Sample P2, originally collected on 12/07/2015, was not redrawn until 1/14/2016. The laboratory did not call the patient until 1/13/2016 for the redraw. Sample P3 was collected on 12/09/2015. There was no indication in the binder records that it was redrawn. Sample P4 was originally collected on 12/15/2015. It was not redrawn until 3/01/2016. The laboratory called the patient on 1/13/2016. Sample P5 was originally collected on 12/16/2015. It was not redrawn until 1/14/2016. The laboratory called the patient on 1/13/2016. Sample P6 was originally collected on 12/17/2015. It was not redrawn until 1/15/2016. The laboratory called the patient on 1/13/2016. c. 10 patient samples (P7-P16) needed redraws in January 2016 because of elevated potassium results. 3 (P7, P8 and P15) of the 10 patients either had no documentation of the recollection date or the sample was recollected more than a month after the original collection date. Sample P7 was originally collected on an unknown date in January 2016. The patient was redrawn on 4/26/2016, 4 months later. There was no documentation of the date the laboratory called the patient to redraw the sample. Sample P8 was collected on 1/26/2016. There was no documentation indicating the sample was recollected. Sample P15 was collected on 1/27/2016. There was no documentation indicating the sample was recollected. d. 8 patient samples (P29-P36)

	collected on 5/18/2016 had to be recollected because of "storage incorrect". There was no documentation of the cause of this error. 1 patient, P32, was not redrawn until 6/21 /2016. 4. During interview via telephone on 1/10/2018 at 8:33 am, the technical consultant stated that she did not see the redraw binder until the Sunday prior to the survey and did not have time to update her quality assurance reviews. She also stated that laboratory personnel did not provide information about redraws during her visits to the laboratory.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of patient records, redraw/recollection records, quality assurance records, panic or critical value reports and interviews with laboratory staff, the laboratory failed to have an effective system to track, assess, and perform corrective actions for patient results that were incorrectly entered into the electronic medical record. This failed practice could result in inaccurate test result reporting to the ordering providers. Findings are: 1. Review of the laboratory binder "Pt redraws and error correction forms" revealed that the laboratory had not used this system since June 2016. TP #1 (Testing person #1) confirmed during interview on 1/10/2018 at 8: 15 am that the laboratory isn't using this system to document redraws or corrected reports. 2. Review of the 2016-2017 panic or critical value reports revealed critical INR (International Normalized Ratio) values were reported for 2 patients (P50 and P51). Both were tested using the CoaguChek XS system which will not report INR values over 8.0. P50 was reported as 20.7 on 4/18/2016 and P51 was reported as 19.0 on 4/19/2016. However, review of the paper log for INR revealed that the result for P50 was 1.7 and the INR for P51 was 1.6, a. There was no documentation in the "Pt redraws and error correction forms" binder that indicated the laboratory had corrected the the INR results for either patient. b. Review of each patient's medical record confirmed that the laboratory had not corrected the results in the electronic medical record. Review of the provider's treatment plan for both patient's indicated that he had not changed the anticoagulant therapy based on the electronic test report. c. During interview with the laboratory director on 1/10/2018 at 9:15 am, he indicated that the testing personnel called him with the the test results. 3. Review of the Review of the laboratory binder "Pt redraws and error correction forms" revealed 4 incidents that required corrected reports. 4 patient samples (P41, P49, P48, and P47) were either mislabeled or ordered under the wrong patient name. a. Sample P41 (complete blood count and lead level) was collected on 2/02/2016. The note indicates that it was "drawn under the wrong patient." The other patient was not identified. The patient was called on 3/07/2016 but no other documentation was on the form indicating the laboratory followed up on the error. b. Sample P49 (rapid Strep test) was collected on 12/14/2015. The document indicated that the medical assistant mislabeled the throat swab with P42's name. There was no documentation that the swab was recollected. c. Sample P48 (rapid Strep test) was collected on 2/26/2016. The document indicated that the throat swab was mislabeled with P44's name but there was no documentation that the swab was recollected. d. Sample P47 (chemistry and complete blood count)

	was ordered and reported on 4/22/2016 as belonging to P45. 4. Record review of monthly quality assurance records revealed no instances of corrected reports issued by the laboratory December 2015- December 2017. 5. During interview via telephone on 1/10/2018 at 8:33 am, the technical consultant stated that she did not see the redraw binder until the Sunday prior to the survey and did not have time to update her quality assurance reviews. She also stated that laboratory personnel did not provide information about redraws during her visits to the laboratory.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of patient records, redraw/recollection records, quality assurance records, panic or critical value reports, and interviews with laboratory staff, the laboratory director failed to ensure a quality assessment program was established and followed by the laboratory. This failed practice could result in delayed or inaccurate test result reporting to the ordering providers. Findings are: 1. The laboratory failed to have an effective system to track, assess, and perform corrective actions for specimens that were mislabeled, ordered incorrectly, or required recollection. See D5293 2. The laboratory failed to have an effective system to track, assess, and perform corrective actions for patient results that were incorrectly entered into the electronic medical record. See D5893 3. Review of the laboratory's policy and procedures revealed no written procedure for quality assessment. Neither the laboratory director nor the office manager commented on this finding during the exit conference on 1/11/2018 at 12:15 pm.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the review of the laboratory policy and procedure manual and interviews with laboratory staff, the laboratory director failed to review and approve the manual since assuming the directorship in 2012. Findings are: 1. Review of the laboratory's policy and procedure manual revealed that the current laboratory director had not signed the following policies and procedures: Proficiency testing- signed by the previous laboratory director/current technical consultant on 03/30/2011. Panic Values - signed by the previous laboratory director/current technical consultant on 04/14

	/2011. Specimen collection and Handling Guidelines - signed by the previous laboratory director/current technical consultant on 03/30/2011. Decision Making Guidelines for Quality Control Hematology - signed by the previous laboratory director/current technical consultant on 04/23/2011. Decision Making Guidelines for Chemistry Quality Control - signed by the previous laboratory director/current technical consultant on 03/30/2011. Microcollection by Skin Puncture - signed by the previous laboratory director/current technical consultant on 03/30/2011. Collection and Testing Priorities - signed by the previous laboratory director/current technical consultant on 03/4/2014. 2. The laboratory director confirmed this finding during interview on 1/10/2018 at 9:15 am.