Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658071	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Soram	1 Mario Braschi, Coamo, PR	

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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: 1. Based on Microscan manufacturer's instructions, incubator temperature records (year 2019) review, technical supervisor interview on June 12, 2019 at 9:45 AM, it was determined that the laboratory failed to follow the Microscan manufacturer's instruction for the temperature incubator when 362 patients urine cultures specimens were processed and reported the growth cultures by the microorganisms identification and susceptibility panels by the Microscan method from February 1, 2019 to May 31, 2019. The findings include: a. The Microscan's manufacturer instructed the laboratory to incubate the microorganisms identification and susceptibility panels at temperature of 35 C + / - 1 C. b. On June 12, 2019 at 9:45 AM, the incubator temperature records showed that the laboratory establish the temperature range of 35 C to 37 C to incubate the Microscan microorganisms identification and susceptibility panels from January 2, 2019 to May 17, 2019. c. The incubator temperature chart showed that the laboratory incubated at 37 C the Microscan panels the following dates: 3 out of 24 days in February 2019, 6 out of 26 days in March 2019, 5 out of 25 days in April 2019 and 3 out of 27 days in May 2019. d. The laboratory technical supervisor confirmed on June 12, 2019 at 9:45 AM, that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at 37 C those days. e. The laboratory processed 362 patients urine cultures specimens and reported the growth cultures by the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to May 31, 2019. 2. Based on Dimension EXL manufacturer's instructions, Cuvette temperature records (years 2018 and 2019) review, technical

	supervisor interview on June 12, 2019 at 10:00 AM, it was determined that the laboratory failed to follow the Dimension EXL manufacturer's instruction when 1,222 patients specimens were processed and reported for comprehensive metabolic panel (CMP) tests and 1,440 patients specimens for Thyroxine (T4), triiodothyronine uptake (T3 uptake) and Thyroid Stimulating Hormone (TSH) tests by the Dimension EXL system from February 1, 2019 to May 30, 2019. a. The Dimension EXL manufacturer's requires the Cuvette temperature range from 36.8 C to 37.2 C. b. On June 12, 2019 at 10:00 AM, the Cuvette temperature records showed that the laboratory processed and reported patients specimens for CMP, T3, T4 and TSH tests out of the required manufacturer temperature range during the following days:12 out 22 days during February 2019, 23 out 26 days during March 2019, 19 out of 25 days during April 2019 and 25 out 27 days during May 2019. c. The technical supervisor confirmed on June 12, 2019 at 10:00 AM, that the laboratory processed patients specimens for CMP, T3, T4 and TSH tests out of the manufacturer temperature range from February 1, 2019 to May 30, 2019. d. The laboratory processed 1,440 patients specimens for CMP tests and 1,440 for T3, T4 and TSH test from February 1, 2019 to May 30, 2019.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, lack of written procedures for preventive maintenance of the Stambio pipette and lack of Stambio pipette preventive maintenance and calibration records and interview with the testing personnel on June 12, 2019 at 11:20 AM, it was determined that the laboratory failed to establish and follow written procedure for the preventive maintenance and calibration of the Stambio pipette, used for the processing of the Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) tests from January 2, 2018 to May 30, 2019. The findings include: 1. On June 12, 2019 at 11:20 AM, its was observed that the laboratory used the Stambio pipette for the processing of the 100 percent of the PT and PTT tests. 2. The laboratory did not have available the Stambio pipette preventive maintenance records nor the Stambio pipette calibration records since January 2, 2018. Also, the laboratory did not have available the writing for those procedures. 3. The testing personnel stated on June 12, 2019 at 11:20 AM, that the preventive maintenance and the calibration were performed but not recorded. 4. The laboratory processed the 100 percent of the PT and PTT tests from January 2, 2018 to May 30, 2019.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on Mycoplasma IGM quality control records (year 2019) review and interview with the technical supervisor on June 12, 2019 at 11:15 AM, it was determined that the laboratory failed to include each day of testing a negative and a positives control materials when 82 out of 82 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from April 23, 2019 to June 3, 2019. The findings include : 1. On June 12, 2019 at 11:15 AM, the Mycoplasma IGM quality control records showed that the laboratory placed in routine use the following lot numbers of Mycoplasma IgM by the Immuno Card Mycoplasma method: a. lot 709030L044 on April 23, 2019. b. lot 709030L049 on May 8, 2019. c. lot 709030L051 on May 24, 2019. 2. The Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing a negative and a positive control materials when 82 out of 82 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from April 23, 2019 to June 3, 2019. 3. The technical supervisor confirmed on June 12, 2019 at 11:15 AM, that the laboratory did not include each day of testing a negative and a positive control materials. She stated, that the laboratory includes a negative and a positive control materials when it places in routine use a new lot of the Immuno Card Mycoplasma reagents Kit.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology culture media plates quality control records review (years 2018 and 2019) and interview with the testing personnel on June 12, 2019 at 9:25 AM, it was found that the laboratory failed to check each batch of culture media plates for sterility when 891 patients specimens for urine culture were processed from January 2, 2018 to May 17, 2019. The finding includes: 1. On June 12, 2019 at 9:25 AM, the bacteriology culture media plates quality control records (Mac Conkey, Blood Agar and XLD) showed that the laboratory did not check each batch of culture media plates for sterility from January 2, 2018 to May 17, 2019. 2. The testing personnel stated on June 12, 2019 at 9:25 AM, that the laboratory checked each batch of culture media plates for sterility but not recorded the results. 3. The laboratory processed 891 patients specimens for urine culture were processed from January 2, 2018 to May 17, 2019.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature records (year 2019),Dimension EXL manufacturer's instructions, Cuvette temperature records (years 2018 and 2019), direct observation, lack of written procedures for preventive maintenance of the Stambio pipette and lack of Stambio pipette preventive maintenance and calibration records, Mycoplasma IGM quality control records (year 2019) , bacteriology culture media plates quality control records review, technical supervisor and technical supervisor on June 12, 2019 at 11:20 AM, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D 5405 (1). (The laboratory did not follow the Microscan manufacturer's instruction for temperature's incubator when 362 patients urine cultures specimens were processed and reported the growth cultures by the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to May 31, 2019). Refer to D5405 (2). (The laboratory did not follow the Dimension EXL manufacturer's instruction when 1,222 patients specimens were processed and reported for comprehensive metabolic panel (CMP) tests and 1,440 patients specimens for Thyroxine (T4), triiodothyronine uptake (T3 uptake) and Thyroid Stimulating Hormone (TSH) tests by the Dimension EXL system from February 1, 2019 to May 30, 2019). Refer to D5429 (The laboratory did not establish nor follow written procedure for the preventive maintenance and calibration of the Stambio pipette, used for the processing of the Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) tests from January 2, 2018 to May 30, 2019). Refer to D5449 (The laboratory did not include each day of testing a negative and a positives control materials when 82 out of 82 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from April 23, 2019 to June 3, 2019). Refer to D5477 (The laboratory did not check each batch of culture media plates for sterility when 891 patients specimens for urine culture were processed from January 2, 2018 to May 17, 2019).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality assessment procedures of the Individualized Quality Control Plan (IQCP) for the Microscan panel quality control and interview with the technical supervisor on June 12, at 9:45 AM, it was determined that the laboratory director failed to establish a review system for the ongoing monitoring of the effectiveness of the Microscan Panel IQCP since January 2, 2018. The finding includes: 1. The laboratory director did not establish a review system for the ongoing monitoring of the effectiveness of the IQCP for the Microscan Panel quality control since January 2, 2018.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for 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 Microscan manufacturer's instructions, incubator temperature records (year 2019),Dimension EXL manufacturer's instructions, Cuvette temperature records (years 2018 and 2019), direct observation, lack of written procedures for preventive maintenance of the Stambio pipette and lack of Stambio pipette preventive maintenance and calibration records, Mycoplasma IGM quality control records (year 2019) , bacteriology culture media plates quality control records review, technical supervisor and technical supervisor on June 12, 2019 at 11:20 AM, it was determined that the technical supervisor failed to ensure that the quality control procedures were maintained throughout the entire testing process. Refer to D 5405 (1). (The laboratory did not follow the Microscan manufacturer's instruction for temperature's incubator when 362 patients urine cultures specimens were processed and reported the growth cultures by the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to May 31, 2019). Refer to D5405 (2). (The laboratory did not follow the Dimension EXL manufacturer's instruction when 1,222 patients specimens were processed and reported for comprehensive metabolic panel (CMP) tests and 1,440 patients specimens for Thyroxine (T4), triiodothyronine uptake (T3 uptake) and Thyroid Stimulating Hormone (TSH) tests by the Dimension EXL system from February 1, 2019 to May 30, 2019). Refer to D5429 (The laboratory did not establish nor follow written procedure for the preventive maintenance and calibration of the Stambio pipette, used for the processing of the Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) tests from January 2, 2018 to May 30, 2019). Refer to D5449 (The laboratory did not include each day of testing a negative and a positives control materials when 82 out of 82 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from April 23, 2019 to June 3, 2019). Refer to D5477 (The laboratory did not check each batch of culture media plates for sterility when 891 patients specimens for urine culture were processed from January 2, 2018 to May 17, 2019).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature records (year 2019),Dimension EXL manufacturer's instructions, Cuvette temperature records (years 2018 and 2019), direct observation, lack of written procedures for preventive maintenance of the Stambio pipette and lack of Stambio pipette preventive maintenance and calibration records, Mycoplasma IGM quality control records (year 2019) , bacteriology culture media plates quality control records review, technical supervisor and technical supervisor on June 12, 2019 at 11:20 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5405 (1). (The laboratory did not follow the Microscan manufacturer's instruction for

	temperature's incubator when 362 patients urine cultures specimens were processed and reported the growth cultures by the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to May 31, 2019). Refer to D5405 (2). (The laboratory did not follow the Dimension EXL manufacturer's instruction when 1,222 patients specimens were processed and reported for comprehensive metabolic panel (CMP) tests and 1,440 patients specimens for Thyroxine (T4), triiodothyronine uptake (T3 uptake) and Thyroid Stimulating Hormone (TSH) tests by the Dimension EXL system from February 1, 2019 to May 30, 2019). Refer to D5429 (The laboratory did not establish nor follow written procedure for the preventive maintenance and calibration of the Stambio pipette, used for the processing of the Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) tests from January 2, 2018 to May 30, 2019). Refer to D5449 (The laboratory did not include each day of testing a negative and a positives control materials when 82 out of 82 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from April 23, 2019 to June 3, 2019). Refer to D5477 (The laboratory did not check each batch of culture media plates for sterility when 891 patients specimens for urine culture were processed from January 2, 2018 to May 17, 2019).