Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0949021	12/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lilith Clinic, The	1670 E Flamingo Rd Ste C, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an off-site CLIA Proficiency Testing (PT) Desk review survey conducted for your facility on December 12, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: successful participation in proficiency testing was not met. The laboratory failed to

	successfully participate in proficiency testing in 2024 for the Hemocue 201+ CLIA waived hemoglobin test, and failed to successfully participate in the specialty of hematology. (see D2130, D2131).
D2128	HEMATOLOGY CFR(s): 493.851(e) (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. This STANDARD is not met as evidenced by: Based on a review of the laboratory 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the laboratory director, the laboratory failed to take and document remedial action to correct the problems associated with the PT failure of the CLIA waived Hemoglobin test during 2024. Findings include: 1. A review of the laboratory records 2024 AAB-MLE PT hematology test event one for the CLIA waived Hemoglobin test performed on the HemoCue 201+ analyzer revealed that the laboratory failed to take and document corrective action for the proficiency testing failures. The laboratory received a score of 60% for the 2024 test event one and 20% for test event three. 2. The laboratory director and testing personnel confirmed the findings during a TEAMS meeting conducted on December 18, 2024 at 9:00 AM. The laboratory performs approximately 2,000 CLIA waived tests annually.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, a review of the CASPER 0153D, and a review of the CASPER 0155D, and an interview with the laboratory director and testing personnel, the laboratory failed to achieve satisfactory performance for the HemoCue 201+ hemoglobin test in two out of three events in 2024. Findings include: 1. A review of the laboratory records for the 2024 AAB-MLE PT for hematology revealed that the laboratory failed to successfully participate in proficiency testing for the HemoCue 201+ CLIA waived hemoglobin test. 2. A review of the CASPER 0153D and the CASPER 0155D revealed that the laboratory failed to successfully participate in the first and third testing event of 2024 for the CLIA waived HemoCue 201+ hemoglobin test. The laboratory received a score of 60% for the 2024 test event one, and a score of 20% for the 2024 test event three. 3. The laboratory director and testing personnel confirmed the findings during a TEAMS meeting conducted on December 18, 2024 at 9:00 AM. The laboratory performs approximately 2000 CLIA waived tests annually.

D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, a review of the CASPER 0153D, and a review of the CASPER 0155D, and an interview with the laboratory director and testing personnel, the laboratory failed to achieve satisfactory performance in the specialty of hematology for two out of three events in 2024. Findings include: 1. A review of the laboratory records for the 2024 AAB-MLE PT for hematology revealed that the laboratory failed to successfully participate in proficiency testing for the specialty of hematology. 2. A review of the CASPER 0153D and the CASPER 0155D revealed that the laboratory failed to successfully participate in the first and third testing event of 2024 for the CLIA waived hematology specialty. The laboratory received a score of 60% for the 2024 test event one, and a score of 20% for the 2024 test event three. 3. The laboratory director and testing personnel confirmed the findings during a TEAMS meeting conducted on December 18, 2024 at 9:00 AM. The laboratory performs approximately 2000 CLIA waived tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: moderate complexity laboratory director was not met. The director failed to ensure that the laboratory was enrolled in the appropriate proficiency testing program for the testing performed, if required. (See D6015) The director failed to ensure that the laboratory successfully participated in the 2024 proficiency testing for the HemoCue 201+ CLIA waived hemoglobin test, and failed to ensure that the laboratory successfully participated in the specialty of hematology. (see D6016) The director failed to ensure that corrective action was taken and documented for the proficiency testing failures for the HemoCue 201+ CLIA waived hemoglobin test for the 2024 test events one and three. (See D2019)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved

	proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of the 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) Records, a review of the 2024 AAB-MLE PT catalog, and an interview with the laboratory director and testing personnel, the director failed to ensure that the laboratory was enrolled in the appropriate program of proficiency testing for the CLIA waived HemoCue 201 Hemoglobin test. Findings include: 1. The laboratory was enrolled in an AAB-MLE PT program intended for non-waived white blood counts (WBC), hemoglobin, and hematocrit. 2. The laboratory performs CLIA waived hemoglobin testing using the HemoCue 201+ analyzer only. 3. AAB-MLE offers a PT program intended for use with the CLIA waived hemoglobin testing on the HemoCue analyzers only. 4. The laboratory director and testing personnel confirmed the findings during a TEAMS meeting conducted on December 18, 2024 at 9:00 AM. The laboratory performs approximately 2,000 CLIA waived tests annually.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the laboratory 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, a review of the CASPER 0153D, and a review of the CASPER 0155D, and an interview with the laboratory director and testing personnel, the laboratory failed to achieve satisfactory performance for the HemoCue 201+ hemoglobin test in two out of three events in 2024. Findings include: 1. A review of the laboratory records for the 2024 AAB-MLE PT for hematology revealed that the laboratory failed to successfully participate in proficiency testing for the HemoCue 201+ CLIA waived hemoglobin test. 2. A review of the CASPER 0153D and the CASPER 0155D revealed that the laboratory failed to successfully participate in the first and third testing event of 2024 for the CLIA waived HemoCue 201+ hemoglobin test. The laboratory received a score of 60% for the 2024 test event one, and a score of 20% for the 2024 test event three. 3. The laboratory director and testing personnel confirmed the findings during a TEAMS meeting conducted on December 18, 2024 at 9:00 AM. The laboratory performs approximately 2000 CLIA waived tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the laboratory 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the laboratory director, the laboratory failed to take and document remedial action to correct the problems associated with the PT failure of the CLIA waived Hemoglobin test during 2024. Findings include: 1. A review of the laboratory records 2024 AAB-MLE PT hematology test event one for the CLIA waived Hemoglobin test performed on the HemoCue 201+ analyzer revealed that the laboratory failed to take and document corrective action for the proficiency testing failures. The laboratory received a score of 60% for the 2024 test event one and 20% for test event three. 2. The laboratory director and testing personnel confirmed the findings during a TEAMS meeting conducted on December 18, 2024 at 9:00 AM. The laboratory performs approximately 2,000 CLIA waived tests annually.