Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2195933	03/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Raazi Clinical Laboratory Llc	7171 Highway 6 N Ste 112, Houston, TX	

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	A validation survey was performed at Raazi Clinical Laboratory LLC on March 23, 2026. Raazi Clinical Laboratory LLC was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of proficiency testing samples; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director;
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's proficiency testing (PT) records, patient test records, and staff interview, the laboratory failed to enroll in Bacteriology proficiency testing for the detection of four of twenty-five pathogens included in the laboratory's molecular diagnostic wound panel in 2025. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing Policy' revealed the following: "This laboratory will subscribe to a CMS-CLIA approved Proficiency Testing (PT) program provider, such as CAP, AAB, API, or other approved providers, for molecular diagnostic testing when available." 2. A review of the laboratory's proficiency testing records revealed the laboratory failed to enroll in

	PT in 2025 for the detection of the following pathogens: - Clostridium novy - Clostridium septicum - Enterobacter aerogenes - Kingella kingae 3. A review of the laboratory's patient test records revealed the laboratory tested 62 patient molecular diagnostic wound panels in 2025, that included the four pathogens listed above. 4. In an interview on 3/23/26 at 11:00 a.m. in the office, after review of the records, the laboratory director confirmed the above findings.
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) (2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to document completion of one of two split sample assessments in 2025 for confirmatory toxicology testing using the LC-MS/MS method. Findings include: 1. A review of the laboratory's policy titled 'Split Analysis: GH Lab' revealed the following: "Compare five samples results with a reference lab to determine the % error (% Difference) of analytes under investigation. The acceptable % error for each individual analyte within each sample is 30%." 2. A review of the laboratory's Split Analysis records for 2025 revealed the laboratory performed two assessments with GH Lab (GHL) on the following dates: - August 2025 - December 2025 3. Further review of the Split Analysis records revealed the laboratory documented the same LC-MS/MS results for the following analytes tested at GHL for August and December: a) Sample 02 - Desmethyltapentadol result: 58.94 - Naltrexone result: 33.39 - Naloxone result: 35.28 - Norhydrocodone result: 59.34 - Ritalinic Acid result: 63.26 - Desmethylcitalopram result: 121.73 - Desmethylvenlafaxine result: 25.95 - Zolpidem Carboxylic acid result: 76.76 - Cotinine result: 57.27 b) Sample 03 - Desmethyltapentadol result: 101.85 - Naltrexone result: 56.76 - Naloxone result: 64.11 - Norhydrocodone result: 117.75 - Ritalinic Acid result: 108.51 - Desmethylcitalopram result: 213.84 - Desmethylvenlafaxine result: 47.1 - Zolpidem Carboxylic acid result: 143.82 - Cotinine result: 105.17 c) Sample 04 - Desmethyltapentadol result: 137.82 - Norhydrocodone result: 144.5 - Ritalinic Acid result: 144.93 - Desmethylcitalopram result: 289.59 - Desmethylvenlafaxine result: 65.41 - Cotinine result: 151.57 d) Sample 05 - Desmethyltapentadol result: 189.06 - Naltrexone result: 124.04 - Norhydrocodone result: 221.23 - Ritalinic Acid result: 206.91 - Desmethylcitalopram result: 376 - Desmethylvenlafaxine result: 89.4 - Cotinine result: 210.36 e) Sample 06 - Desmethyltapentadol result: 253.14 - Naltrexone result: 182.65 - Norhydrocodone result: 306.98 - Ritalinic Acid result: 279.43 - Desmethylcitalopram result: 576.02 - Desmethylvenlafaxine result: 122.84 - Cotinine result: 304.4 4. In an interview on 3/23/26 at 11:40 a.m. in the office, after review of the records, the technical supervisor (as identified on the CMS-209) confirmed the results from GHL were not entered on the Split Analysis spreadsheet for the December assessment, stating the % error calculations were not accurate and assessed for acceptability. Key: LC-MS/MS = Liquid Chromatography-Mass Spectrometry/Mass Spectrometry
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)

	(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records, and staff interview, the laboratory failed to document performance of a self-evaluation of analytes that were 'not graded' by the proficiency testing program for two of three Microbiology proficiency testing events in 2025. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing Policy' revealed the following: "When the result received is 'ungraded' or 'educational challenge', evaluate the result against the participant summary report to determine the laboratory's performance and document corrective action if the result failed to agree with the majority of the participants." 2. A review of the American Proficiency Institute's Performance Evaluation revealed the following: "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for analytes that have not been graded." 3. A review of the laboratory's API results from 2025 revealed the following Microbiology proficiency testing events that included analytes that were scored as 'not graded' and the laboratory failed to have documentation of a self-evaluation: a) 2025 Microbiology- 2nd Event - Molecular Resist. Genes- Urine: Gene KPC samples: UTI-06, UTI-09 - Molecular Resist. Genes- Urine: Gene mecA samples: UTI-06, UTI-07, UTI-08, UTI-10 - Molecular Resist. Genes- Urine: Gene mefA samples: UTI-06, UTI-07, UTI-08, UTI-09, UTI-10 - Molecular Resist. Genes- Urine: Gene OXA-48 samples: UTI-06, UTI-09 - Molecular Resist. Genes- Urine: Gene qnrA samples: UTI-06, UTI-09 - Molecular Resist. Genes- Urine: Gene qnrS samples: UTI-06, UTI-09 - Molecular Resist. Genes- Urine: Gene vanA samples: UTI-06, UTI-07, UTI-08, UTI-10 - Molecular Resist. Genes- Urine: Gene vanB samples: UTI-06, UTI-07, UTI-08, UTI-09, UTI-10 b) 2025 Microbiology- 3rd Event - Molecular Resist. Genes- Urine: Gene IMP samples: UTI-12, UTI-13, UTI-15 - Molecular Resist. Genes- Urine: Gene KPC samples: UTI-12, UTI-13, UTI-15 - Molecular Resist. Genes- Urine: Gene mecA samples: UTI-11, UTI-13, UTI-14, UTI-15 - Molecular Resist. Genes- Urine: Gene mefA samples: UTI-12, UTI-13, UTI-15 - Molecular Resist. Genes- Urine: Gene OXA-48 samples: UTI-12, UTI-13, UTI-15 - Molecular Resist. Genes- Urine: Gene qnrA samples: UTI-12, UTI-13, UTI-15 - Molecular Resist. Genes- Urine: Gene qnrS samples: UTI-12, UTI-13, UTI-15 - Molecular Resist. Genes- Urine: Gene vanA samples: UTI-11, UTI-12, UTI-13, UTI-14 - Molecular Resist. Genes- Urine: Gene vanB samples: UTI-11, UTI-12, UTI-13, UTI-14, UTI-15 4. In an interview on 3/23 /26 at 10:45 a.m. in the office, after review of the records, the laboratory director confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies, laboratory records, and staff interview, the laboratory failed to meet pre-analytic system requirements for one of six molecular diagnostic test panels performed in December 2025. Findings include: 1. The laboratory failed to ensure that patient urine specimens were received, handled, and accepted in accordance with established criteria to maintain specimen integrity. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to ensure that patient urine specimens were received, handled, and accepted in accordance with established criteria to maintain specimen integrity, as evidenced by lack of defined acceptability criteria for frozen specimens and lack of documentation of specimen transport conditions for molecular diagnostic testing for 22 of 51 samples reviewed in December 2025. Findings include: 1. A review of the laboratory's policy titled 'Specimen Collection and Shipping' revealed the following: "Urinary Tract Infection (UTI): Urine Stability Criteria: - Up to 24 hours at Room Temperature after collection - Up to 72 hours at 2 to 8 C after collection" 2. In an interview on 3/23/26 at 2:15 p.m. in the laboratory, when asked how the laboratory receives urine samples for testing, the general supervisor stated the laboratory usually receives patient urine specimens at room temperature and, at times, facilities freeze and ship the specimens frozen. 3. Further review of the laboratory's policies revealed the laboratory failed to include acceptability criteria for frozen urine samples. 4. A review of the laboratory's records for December 2025 revealed the following patient urine samples had no indication as to whether the samples were shipped at room temperature, refrigerated, or frozen and were resulted beyond the acceptable 72 hour time frame per the laboratory's policy: - Patient: 2512100104 Collected 12/17/25 at 15:11 Received: 12/22/25 at 09:30 Elapsed time: 114 hours - Patient: 2512100105 Collected 12/17/25 at 10:00 Received: 12/22/25 at 09:30 Elapsed time: 119 hours - Patient: 2512100107 Collected 12/17/25 at 15:57 Received: 12/22 /25 at 11:10 Elapsed time: 115 hours - Patient: 2512100108 Collected 12/17/25 at 16: 16 Received: 12/22/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100109 Collected 12/17/25 at 16:21 Received: 12/22/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100110 Collected 12/17/25 at 16:02 Received: 12/22/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100111 Collected 12/17/25 at 16:07 Received: 12/22 /25 at 11:10 Elapsed time: 115 hours - Patient: 2512100112 Collected 12/17/25 at 16: 13 Received: 12/22/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100113 Collected 12/17/25 at 16:10 Received: 12/22/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100114 Collected 12/17/25 at 16:05 Received: 12/22/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100115 Collected 12/17/25 at 15:59 Received: 12/22

	/25 at 11:10 Elapsed time: 115 hours - Patient: 2512100116 Collected 12/18/25 at 19: 41 Received: 12/22/25 at 11:10 Elapsed time: 87 hours - Patient: 2512100117 Collected 12/18/25 at 18:48 Received: 12/22/25 at 11:10 Elapsed time: 88 hours - Patient: 2512100118 Collected 12/18/25 at 19:23 Received: 12/22/25 at 11:10 Elapsed time: 87 hours - Patient: 2512100119 Collected 12/18/25 at 19:50 Received: 12/22/25 at 11:10 Elapsed time: 87 hours - Patient: 2512100120 Collected 12/18/25 at 18:55 Received: 12/22/25 at 11:10 Elapsed time: 88 hours - Patient: 2512100121 Collected 12/18/25 at 19:48 Received: 12/22/25 at 11:10 Elapsed time: 87 hours - Patient: 2512100122 Collected 12/18/25 at 18:53 Received: 12/22/25 at 11:10 Elapsed time: 88 hours - Patient: 2512100123 Collected 12/18/25 at 18:28 Received: 12/22/25 at 11: 10 Elapsed time: 88 hours - Patient: 2512100124 Collected 12/18/25 at 19:12 Received: 12/22/25 at 11:10 Elapsed time: 87 hours - Patient: 2512100125 Collected 12/18/25 at 19:38 Received: 12/22/25 at 11:10 Elapsed time: 87 hours - Patient: 2512100126 Collected 12/18/25 at 19:44 Received: 12/22/25 at 11:10 Elapsed time: 87 hours 5. In an interview on 3/23/26 at 1:50 p.m. in the office, after review of the records, the laboratory director confirmed the above findings. Key: C = Degrees Celsius
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory director failed to provide overall management and direction of the laboratory for two of six molecular diagnostic test panels performed in 2025. Findings include: 1. The laboratory director failed to ensure pre-analytic systems provided quality results for one of six molecular diagnostic test panels performed by the laboratory in December 2025. Refer to D6082. 2. The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for four of twenty-five pathogens in the specialty of Bacteriology in 2025. Refer to D6088.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory director failed to ensure pre-analytic systems provided quality results for one of six molecular diagnostic test panels performed by the laboratory in December 2025. Findings include: 1. The laboratory failed to ensure that patient urine specimens were received, handled, and accepted in accordance with established criteria to maintain specimen integrity. Refer to D5311.

D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing records and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for four of twenty-five pathogens in the specialty of Bacteriology in 2025. Refer to D2000.