Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2182509	**(X3) Date Survey Completed** 10/29/2020
Name of Provider or Supplier Ut Physicians Utpb Clinic	**Street Address, City, State** 6410 Fannin Street, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Academy of Family Physicians proficiency testing records from 2020 third event and staff interview, it was revealed the laboratory failed to test proficiency testing samples the same as patient samples. The findings were: 1. A review of the laboratory's American Academy of Family Physicians proficiency testing records from 2020 third event revealed the laboratory tested the 2 of 2 proficiency samples, multiple times by differing testing personnel (as listed on CMS Form-209). 2020 event 3 Sample CVAB -11 Tested: 10/27/2020 by TP #1 Tested: 10/27/2020 by TP #2 Tested: 10/27/2020 by TP #3 Sample CVAB - 12 Tested: 10/27/2020 by TP #1 Tested: 10/27/2020 by TP #2 Tested: 10/27/2020 by TP

	#3 2. An interview with the clinical safety coordinator on 10/29/2020 at 1115 hours in the break room revealed the laboratory tested patient samples multiple times with multiple testing personnel. She agreed that a patient sample would not be run by all testing personnel. This confirmed the findings. Key: TP - Testing Personnel CMS - Center for Medicare and Medicaid Services
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing (PT) records, review of the laboratory policy, and confirmed interview of facility personnel, the laboratory failed to have documentation of the laboratory director attesting to the routine integration of the samples for 1 of 1 testing event. The findings were: 1. A review of the laboratory's (AAFP) proficiency testing records from 2020 (event 3) revealed the attestation statement was not signed by the laboratory director. 2. A review of the laboratory policy " UT Physicians UTPB Clinic Proficiency Testing" revealed no documentation that the testing person or laboratory director must attest to analyzing the proficiency samples within the routine integration of the laboratory's workload. 3. An interview with the clinical safety coordinator on 10 /29/2020 at 1115 hours in the breakroom after her review of the records confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to document verification studies for the Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette. Refer to D5421 2. The laboratory failed to provide documentation of performing quality control each day of patient testing for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5449
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of review of the manufacturer's instructions for the Healgen COVID-19 IgG/IgM Rapid Test Cassette, review of the laboratory's environmental records from August 20, 2020 to October 29, 2020, and staff interview, the laboratory failed to include: A. Humidity monitoring for storage room B. Temperature and Humidity monitoring for Testing area The findings were: A. Humidity monitoring for storage room 1. A review of the manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette (Ref GCCOV-402a) under " Warnings and Precautions" states "Humidity and Temperature can adversely affect results (especially with an RH over 80%) Testing must be performed within one hour after opening the pouch." 2. A review of the laboratory environmental records for Room 4 revealed no documentation of humidity for 15 of 15 days the laboratory performed testing. 3. A review of patient records, revealed 122 patient samples were tested from August 20, 2020 to October 29, 2020. See Patient Alias List 4. An interview with the clinical safety coordinator on 10/29/2020 at 1047 hours in the break room- after her review of the records - confirmed the findings. B. Temperature and humidity Testing area 1. A review of the manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette (Ref GCCOV-402a) under " Warnings and Precautions" states "This test should be performed at 15 to 30 degrees celsius. Humidity and Temperature can adversely affect results (especially with an RH over 80%) Testing must be performed within one hour after opening the pouch." 2. Observation and review of the laboratory environmental records for the testing room, revealed no documentation or mechanism to monitor humidity and temperature for 15 of 15 days the laboratory performed testing. 3. A review of patient records, revealed 122 patient samples were tested from August 20, 2020 to October 29, 2020. See Patient Alias List 4. An interview with the clinical safety coordinator on 10/29/2020 at 1047 hours in the break room- after her review of the records - confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory failed to document verification studies for 1 of 1 test (Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette) prior to patient testing. Findings were: 1. Review of the Instructions for use

	for the Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette (Revision Date: 2020-5-2) under Intended use revealed "Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests." 2. Review of the laboratory records available revealed no documentation of accuracy nor precision for the qualitative test for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette. 3. Review of the patient test logs from August 2020 to October 2020 revealed the laboratory performed 122 patients. Refer to patient alias list. 4. An interview with the clinical safety coordinator on 10/29/20 at 1040 hours in the break room confirmed the above findings. She was unaware an EUA authorized test required verification studies. key: EUA - Emergency Use Authorization FDA - Food and Drug Administration
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 review of the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory failed to document a positive and negative quality control every day of patient testing for the Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette. Findings were: 1. Review of the Instructions for use for the Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette (Revision Date: 2020-5-2) under Quality Control revealed "it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations." 2. Review of the laboratory records from August 2020 to October 2020 revealed no documentation of positive and negative control for the qualitative test for Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette. 3. Review of the patient test logs from August 2020 to October 2020 revealed the laboratory performed 122 patients. Refer to patient alias list. 4. An interview with the clinical safety coordinator on 10/29/20 at 1040 hours in the break room confirmed the above findings. She was unaware an external control was required for EUA authorized tests. key: EUA - Emergency Use Authorization FDA - Food and Drug Administration
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 review of the manufacturer's instructions, laboratory records, quality control

	records, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6013, D6020
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory director failed to ensure the laboratory documented verification studies for the Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette prior to patient testing. Refer to D5421
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory director failed to ensure the laboratory documented a positive and negative quality control every day of patient testing for the Healgen Scientific LLC COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5449
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted (Form CMS 209), review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 3 testing personnel to perform moderate complexity testing (refer to D6065). Key: CMS - Centers for Medicare and Medicaid Services

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted (Form CMS 209), review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 3 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted (Form CMS 209) on Oct 29, 2020 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's personnel records revealed 1 of 3 testing personnel did not have documentation of education to qualify them to perform moderate complexity testing. 3. Review of the personnel records for testing personnel three (as listed on Form CMS 209) revealed the records available for review was a license. 4. An interview with the clinical safety coordinator on 10/29/2020 at 09:40 hours in the break room confirmed the laboratory did not have documentation of education for testing personnel #3 Key: CMS - Centers for Medicare and Medicaid Services