Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1044073	11/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
United Laboratory Services Corp	7095 Sw 47th St Bldg B, Miami, FL	

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	An unannounced complaint survey, #2020012381 conducted on 11/5/20 to 11/10/20 at United Laboratory Services Corp. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. The following conditions were cited: -D3000 -D5400
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the State of Florida Emergency Rule to report COVID 19 tests results to the Department of Health (DOH). See 3009
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with owner, the laboratory failed to follow the State of Florida Emergency Rule to report all positive and negative Coronavirus 19 (COVID-19) test results immediately to the Department of Health (DOH) for 4 positive and 59 negative out of 159 cases tested using Biofire Film Array Coronavirus

	2019 (COVID-19). Findings include: -Record review revealed that the laboratory started to report COVID 19 results using Biofire Film Array on 7/1/2020. -The laboratory tested 159 cases from 7/1/2020 to 11/2/2020. -Review of reports sent to the Health County from 7/1/2020 to 11/02/2020 revealed that the laboratory failed to report 4 positive (339789, 339883, 340338, 340349) and 59 negative (339321, 339326, 339325, 339701, 339702, 339703, 339704, 339779, 339781, 339810, 339822, 339853, 339919, 339999, 340193, 340089, 341617, 342995, 342996, 343019, 343020, 343021, 343022, 343186, 343193, 343250, 343349, 343350, 343354, 343359, 343501, 343521, 343527, 343599, 343605, 343606, 343635, 343737, 343898, 343899, 343908, 343916, 343932, 343933, 343934, 344000, 344066, 344196, 345234, 346340, 346381, 346407, 346527, 346528, 346529, 346530, 346531, 346875, 346953) COVID 19 cases. During an interview on 11/5 /2020 at 5:30 PM, the laboratory owner, confirmed that the laboratory failed to report the COVID-19 results of reference.
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 record review and interview, the laboratory failed to complete COVID -19 antigen testing validations for Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette and FaStep COVID-19 IgG/IgM Rapid Test Device in 2020. (See 5421) Based on record review and interview, the laboratory failed to document and perform external positive and negative controls for Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System from 5/6/2020 to 6/21/2020, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette from 5/20/2020 to 7/03/2020 and FaStep Covid-19 IgG/IgM Rapid Test Device from 7/20/2020 to 10/20/2020 . (See 5449)
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 record review and owner interview, the laboratory failed to complete COVID -19 antigen testing validations for Zeus Scientific Rapid SARS-CoV-2 IgM /IgG Test System, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette

	and FaStep COVID-19 IgG/IgM Rapid Test Device in 2020 . Finding Included : Review of Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System validation revealed no documentation for validating patient samples for testing since 5/6/2020. Review of Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette validation revealed no documentation for validating patient samples for testing since 5 /20/2020. Review and FaStep COVID-19 IgG/IgM Rapid Test Device validation revealed no documentation for validating patient samples for testing since 7/20/2020. Review of COVID-19 testing log revealed Zeus Scientific Rapid SARS-CoV-2 IgM /IgG Test System in use from 5/6/2020 to 6/21/2020 , Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette in use from 5/20/2020 to 7/03/2020 and FaStep COVID-19 IgG/IgM Rapid Test Device in use from 7/20/2020 to 10/20/2020. During an interview on 11/10/2020 at 4:49pm, the owner confirmed the validation was not completed for Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette and FaStep COVID-19 IgG/IgM Rapid Test Device in 2020.
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 record review and interview, the laboratory failed to document and perform external positive and negative controls for Zeus Scientific Rapid SARS-CoV-2 IgM /IgG Test System from 5/6/2020 to 6/21/2020, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette from 5/20/2020 to 7/03/2020 and FaStep Covid-19 IgG /IgM Rapid Test Device from 7/20/2020 to 10/20/2020 . Findings Included : Review of COVID-19 External Quality Control for FaStep revealed that no negative and positive controls documented from 7/20/2020 to 10/20/2020. Review of COVID-19 External Quality Control for Zeus revealed that no negative and positive controls documented from 5/6/2020 to 6/21/2020. Review of COVID-19 External Quality Control for Healgen revealed that no negative and positive controls documented from 7/20/2020 to 10/20/2020. Review of COVID-19 testing log revealed Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System in use from 5/6/2020 to 6/21/2020, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette in use from 5/20 /2020 to 7/03/2020 and FaStep COVID-19 IgG/IgM Rapid Test Device in use from 7 /20/2020 to 10/20/2020. During an interview on 11/10/2020 at 4:49pm , the owner confirmed failure to document and perform external positive and negative controls for Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System from 5/6/2020 to 6/21 /2020, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette from 5/20 /2020 to 7/03/2020 and FaStep Covid-19 IgG/IgM Rapid Test Device from 7/20/2020 to 10/20/2020.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 record review and interview, the laboratory director (LD) failed to sign and review validations that were in use for Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette and FaStep Covid-19 IgG/IgM Rapid Test Device . Findings Included : Review of Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System validation lacked documentation of a review and signature by LD. Review of Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette validation lacked documentation of a review and signature by LD. Review of FaStep COVID-19 IgG/IgM Rapid Test Device validation lacked documentation of a review and signature by LD. Review of COVID-19 testing log revealed Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System was in use from 5 /6/2020 to 6/21/2020. Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette was in use from 5/20/2020 to 7/03/2020 . FaStep COVID-19 IgG/IgM Rapid Test Device was in use from 7/20/2020 to 10/20/2020 . During an interview on 11/10 /2020 at 4:49pm , the owner confirmed the LD did not sign and review validations for Zeus Scientific Rapid SARS-CoV-2 IgM/IgG Test System, Healgen Scientific LLC COVID-19 IgG /IgM Rapid Test Cassette and FaStep COVID-19 IgG/IgM Rapid Test Device.