Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D1012328	**(X3) Date Survey Completed** 05/23/2019
Name of Provider or Supplier Canadian Valley Family Care	**Street Address, City, State** 1491 Health Center Parkway, Yukon, OK	
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 recertification survey was performed on 05/23/19. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: ANALYTIC SYSTEMS 493.1403; D6000: LABORATORY DIRECTOR The findings were reviewed with the laboratory manager at the conclusion of the survey.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure that proficiency testing samples were tested by personnel who routinely performed patient testing. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed the following: (a) CBC (Complete Blood Count) testing using the Sysmex pocH-100i analyzer; (b) PSA (Prostate Specific Antigen), Testosterone, Vitamin D, TSH (Thyroid Stimulating Hormone), and Free T4 testing using the Beckman Coulter Access 2 analyzer. (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory prior to the survey, with the laboratory manager. The laboratory manager stated that 2 persons performed the above patient testing in the laboratory (laboratory manager/testing person #1 and testing person #2); (3) The surveyor then reviewed proficiency testing records and identified that 7 of 9 events performed in 2017, 2018, and 2019 had been tested by the same person (laboratory manager/testing person #1) as follows: (a) Third 2017 Hematology Event - 5 of 5 samples (HSY-12, HSY-13, HSY-14, HSY-15, HSY-16) (b) First 2018 Hematology Event - 5 of 5 samples (HSY-01, HSY-02, HSY-03, HSY-04, HSY-05) (c) Second 2018 Hematology Event - 5 of 5 samples (HSY-06, HSY-07,

	HSY-08, HSY-09, HSY-10) (d) Third 2018 Hematology Event - 5 of 5 samples (HSY-11, HSY-12, HSY-13, HSY-14, HSY-15) (e) First 2018 Chemistry Miscellaneous Event - 3 of 3 samples (IA-01, IA-02, IA-03) (f) Second 2018 Chemistry Core Event - 5 of 5 samples (CH-06, CH-07, CH-08, CH-09, CH-10) (g) Third 2018 Chemistry Core Event - 5 of 5 samples (CH-11, CH-12, CH-13, CH-14, CH-15) (4) The findings were reviewed with the laboratory manager who stated the proficiency testing samples had been tested by the laboratory manager, as indicated above.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to test proficiency testing samples the same number of times that patient samples were tested. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed the following: (a) CBC (Complete Blood Count) testing using the Sysmex pocH-100i analyzer; (b) PSA (Prostate Specific Antigen), Testosterone, Vitamin D, TSH (Thyroid Stimulating Hormone), and Free T4 testing using the Beckman Coulter Access 2 analyzer. (2) Later during the survey, the surveyor reviewed proficiency testing records for 9 events (Third 2017, First 2018, Second 2018, Third 2018, and First 2019 Hematology Events; First 2018 and Second 2018 Chemistry Miscellaneous Events; Second 2018 and Third 2018 Chemistry Core Events) and identified the specimens had been tested multiple times for 8 of 9 events as follows: (a) Third 2017 Hematology Event (i) Sample HSY-11 was tested three times (03:01 pm on 11/27/17, 03:04 pm on 11/27 /17, and 09:17 am on 11/28/17) with the results reported to the proficiency testing program as follows: (aa) The WBC (White Blood Cell), RBC (Red Blood Cell), Hemoglobin, Hematocrit, MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), LYM%, MXD%, and NEUT% results obtained from the 03:01 pm testing on 11/27/17 had been reported; (bb) The MCV (Mean Corpuscular Volume) result obtained from the 03:04 pm testing on 11/27/17 had been reported; (cc) The Platelet result obtained from the 09:17 am testing on 11/28 /17 had been reported. (ii) Sample HSY-12 was tested three times (03:08 pm on 11/27 /17, 03:12 on 11/27/17, and 09:23 am on 11/28/17) with the results reported to the proficiency testing program as follows: (aa) The WBC, Hemoglobin, Hematocrit, MCV, Platelet, MXD%, and NEUT% results obtained from the 03:08 pm testing on 11 /27/17 had been reported; (bb) The RBC, MCH, MCHC, and LYM% results obtained from the 09:23 am testing on 11/28/17 had been reported. (iii) Sample HSY-13 was tested three times (03:26 pm on 11/27/17, 03:29 pm on 11/27/17, and 09:29 am on 11 /28/17) with the results reported to the proficiency testing program as follows: (aa) The WBC, Hematocrit, MCV, MCH, MCHC, LYM%, MXD%, and NEUT% results obtained from the 03:26 pm testing on 11/27/17 had been reported; (bb) The RBC and Platelet results obtained from the 03:31 pm testing on 11/27/17 had been reported; (cc) The Hemoglobin result obtained from the 09:29 am testing on 11/28/17 had been reported. (iv) Sample HSY-14 was tested three times (03:42 pm on 11/27/17, 03:47 pm on 11/27/17, and 09:38 am on 11/28/17) with the results reported to the proficiency testing program as follows: (aa) The MCH and MCHC results obtained from the 03:42 testing on 11/27/17 had been reported; (bb) The WBC, RBC, Hemoglobin, Hematocrit, MCV, Platelet, LYM%, MXD% and NEUT% results

obtained from the 03:47 pm testing on 11/27/17 had been reported. (v) Sample HSY-15 was tested three times (03:50 pm on 11/27/17, 03:53 pm on 11/27/17, and 09:46 am on 11/28/17) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, LYM%, and MXD% results obtained from the 03:50 pm testing on 11/27/17 had been reported; (bb) The Platelet result obtained from the 03:53 pm testing on 11/27/17 had been reported; (cc) The NEUT% result obtained form the 09:46 am testing on 11/28 /17 had been reported. (b) First 2018 Hematology Event (i) Sample HSY-01 was tested three times (08:37 am, 08:45 am, and 08:48 am on 03/22/18) with the results reported to the proficiency testing program as follows: (aa) The WBC and Hematocrit results obtained from the 08:37 testing had been reported; (bb) The RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 08:48 testing had been reported. (ii) Sample HSY-02 was tested two times (09:01 am and 09:03 on 03/22/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:03 am testing had been reported. (iii) Sample HSY-03 was tested two times (09:09 am and 09:14 am on 03/22/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:14 am testing had been reported. (iv) Sample HSY-04 was tested two times (09:17 am and 09:21 am on 03/22/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:21 am testing had been reported. (v) Sample HSY-05 was tested two times (09:25 am and 09:28 am on 03/22/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09: 25 am testing had been reported. (c) Second 2018 Hematology Event (i) Sample HSY-06 was tested two times (09:11 am and 09:15 am on 07/24/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:15 am testing had been reported. (ii) Sample HSY-07 was tested two times (09:21 am and 09:25 am on 07/24/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09: 25 am testing had been reported. (iii) Sample HSY-08 was tested two times (09:32 am and 09:38 am on 07/24/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:38 am testing had been reported. (iv) Sample HSY-09 was tested two times (09:41 am and 09:45 am on 07/24 /18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:45 am testing had been reported. (v) Sample HSY-10 was tested two times (09:48 am and 09:57 am on 07/24/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:48 am testing had been reported. (d) Third 2018 Hematology Event (i) Sample HSY-11 was tested three times (02:42 pm, 02:45 pm, and 02:49 pm on 11/21/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 02:49 pm testing had been reported. (ii) Sample HSY-12 was tested three times (02:53 pm, 02:59 pm, and 03:02 pm on 11/21 /18) with the results reported to the proficiency testing program as follows: (aa) The

WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 02:53 pm testing had been reported. (iii) Sample HSY-13 was tested three times (03:14 pm, 03:19 pm, and 03:23 pm on 11/21/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 03:23 pm testing had been reported. (iv) Sample HSY-14 was tested three times (03:27 pm, 03:30 pm, and 03:38 pm on 11/21/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 03:30 pm testing had been reported. (v) Sample HSY-15 was tested three times (03:37 pm, 03:42 pm, and 03:50 pm on 11/21/18) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 03:39 pm testing had been reported. (e) First 2019 Hematology Event (i) Sample HSY-01 was tested three times (08:55 am, 09:23 am, and 09:44 am on 03/26/19) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:23 am testing had been reported. (ii) Sample HSY-02 was tested three times (08:59 am, 09:27 am, and 09:49 am on 03/26/19) with the results reported to the proficiency testing program as follows: (aa) The Platelet result obtained from the 08:59 am testing had been reported; (bb) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, LYM%, MXD%, and NEUT% results obtained from the 09:27 am testing had been reported. (iii) Sample HSY-03 was tested three times (09:03 am, 09:31 am, and 09:53 am on 03/26/19) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:31 am testing had been reported. (iv) Sample HSY-04 was tested three times (09:09 am, 09:35 am, and 09:57 am on 03/26/19) with the results reported to the proficiency testing program as follows: (aa) The Platelet result obtained from the 09:35 am testing had been reported; (bb) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, LYM%, MXD%, and NEUT% results obtained from the 09:57 am testing had been reported. (v) Sample HSY-05 was tested three times (09:14 am, 09:39 am, and 10:03 am on 03/26/19) with the results reported to the proficiency testing program as follows: (aa) The WBC, RBC, Hemoglobin, MCV, MCH, MCHC, Platelet, LYM%, MXD%, and NEUT% results obtained from the 09:39 am testing had been reported. (f) Second 2018 Chemistry Miscellaneous Event (i) Sample IA-04 was tested three times for PSA and Testosterone; and two times for Vitamin D on 10/30/18 (PSA was tested at 10:28 am, 10:30 am, and 11:59 am; Testosterone was tested at 10:20 am, 10:30 am, and 11:53 am; Vitamin D was tested at 10:49 am, and 10:51 am) with the results reported to the proficiency testing program as follows: (aa) The PSA result obtained from the 11:59 am testing had been reported; (bb) The Testosterone result obtained from the 10:20 am testing had been reported; (cc) The Vitamin D result obtained from the 10:51 am testing had been reported. (ii) Sample IA-05 was tested three times for PSA and Testosterone; and two times for Vitamin D on 10/30/18 (PSA was tested at 10:29 am, 10:30 am, and 12:00 pm; Testosterone was tested at 10:20 am, 10:22 m, and 11:53 am; Vitamin D was tested at 10:50 am and 10:51 am) with the results reported to the proficiency testing program as follows: (aa) The PSA result obtained from the 10:30 am testing had been reported; (bb) The Testosterone result obtained from the 10:20 am testing had been reported; (cc) The Vitamin D result obtained from the 10:51 am testing had been reported. (iii) Sample IA-06 was tested three times for PSA and Testosterone; and two times for Vitamin D on 10/30/18 (PSA was tested at 10:29 am, 10:31 am, and 12:01 pm; Testosterone was tested at 10:21 am, 10:23 am, and 11:54 am; Vitamin D was tested at 10:50 am and 10:51 am) with the results reported to the

proficiency testing program as follows: (aa) The PSA result obtained from the 12:01 am testing had been reported; (bb) The Testosterone result obtained from the 10:23 am testing had been reported; (cc) The Vitamin D result obtained from the 10:51 am testing had been reported. (g) Second 2018 Chemistry Core Event (i) Sample CH-06 was tested two times for TSH and Free T4 on 06/04/18 (TSH was tested at 03:42 pm and 03:48 pm; Free T4 was tested at 03:26 pm and 03:32 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 3.86, which was the calculated average of the result obtained from the 03:42 pm testing (3.94) and the result obtained from the 03:48 pm testing (3.78); (bb) The Free T4 result that had been reported was 2.84, which was the calculated average of the result obtained from the 03:26 pm testing (2.71) and the result obtained from the 03:32 pm testing (2.96). (ii) Sample CH-07 was tested two times for TSH and Free T4 on 06/04/18 (TSH was tested at 03:44 pm and 03:50 pm; Free T4 was tested at 03:27 pm and 03:33 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 1.81, which was the calculated average of the result obtained from the 03:42 pm testing (1.77) and the result obtained from the 03:48 pm testing (1.85); (bb) The Free T4 result that had been reported was 3.20, which was the calculated average of the result obtained from the 03:26 pm testing (3.24) and the result obtained from the 03:32 pm testing (3.10). (iii) Sample CH-08 was tested two times for TSH and Free T4 on 06/04/18 (TSH was tested at 03:45 pm and 03:51 pm; Free T4 was tested at 03:29 pm and 03:35 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 5.44, which was the calculated average of the result obtained from the 03:45 pm testing (5.36) and the result obtained from the 03:51 pm testing (5.52); (bb) The Free T4 result that had been reported was 2.74, which was the calculated average of the result obtained from the 03:29 pm testing (2.75) and the result obtained from the 03:35 pm testing (2.73). (iv) Sample CH-09 was tested two times for TSH and Free T4 on 06/04/18 (TSH was tested at 03:46 pm and 03:52 pm; Free T4 was tested at 03:30 pm and 03:36 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 1.09, which was the calculated average of the result obtained from the 03:46 pm testing (1.07) and the result obtained from the 03:52 pm testing (1.10); (bb) The Free T4 result that had been reported was 3.32, which was the calculated average of the result obtained from the 03:30 pm testing (3.25) and the result obtained from the 03:36 pm testing (3.40). (v) Sample CH-10 was tested two times for TSH and Free T4 on 06/04/18 (TSH was tested at 03:47 pm and 03:54 pm; Free T4 was tested at 03:31 pm and 03:38 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 5.08, which was the calculated average of the result obtained from the 03:47 pm testing (5.08) and the result obtained from the 03:54 pm testing (5.09); (bb) The Free T4 result that had been reported was 2.75, which was the calculated average of the result obtained from the 03:31 pm testing (2.70) and the result obtained from the 03:38 pm testing (2.75). (h) Third 2018 Chemistry Core Event (i) Sample CH-11 was tested two times for TSH and Free T4 on 09/11/18 (TSH was tested at 02:26 pm and 02:32 pm; Free T4 was tested at 02:10 pm and 02:16 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result obtained from the 02:32 pm testing had been reported (1.25); (bb) The Free T4 result that had been reported was 3.4, which was the calculated average of the result obtained from the 02:10 pm testing (3.42) and the result obtained from the 02:16 pm testing (3.38). (ii) Sample CH-12 was tested two times for TSH and Free T4 on 09/11/18 (TSH was tested at 02:27 pm and 02:33 pm; Free T4 was tested at 02:11 pm and 02:17 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 4.20, which was the calculated average of the result obtained from the 02:27 pm

	testing (4.09) and the result obtained from the 02:33 pm testing (4.30); (bb) The Free T4 result that had been reported was 2.9, which was the calculated average of the result obtained from the 02:11 pm testing (2.92) and the result obtained from the 02:17 pm testing (2.95). (iii) Sample CH-13 was tested two times for TSH and Free T4 on 09/11/18 (TSH was tested at 02:28 pm and 02:34 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 5.62, which was the calculated average of the result obtained from the 02:28 pm testing (5.82) and the result obtained from the 02:34 pm testing (5.43); (bb) The Free T4 result that had been reported was 2.8, which was the value obtained from the 02:12 pm testing and the 02:18 pm testing. (iv) Sample CH-14 was tested two times for TSH and Free T4 on 09/11/18 (TSH was tested at 02:29 pm and 02:35 pm; Free T4 was tested at 02:17 pm and 02:20 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 2.82, which was the calculated average of the result obtained from the 02:29 pm testing (2.79) and the result obtained from the 02:35 pm testing (2.85); (bb) The Free T4 result that had been reported was 3.3, which was the calculated average of the result obtained from the 02:17 pm testing (3.25) and the result obtained from the 02:20 pm testing (3.27). (v) Sample CH-15 was tested two times for TSH and Free T4 on 09/11/18 (TSH was tested at 02:31 pm and 02:37 pm; Free T4 was tested at 02:14 pm and 02:21 pm) with the results reported to the proficiency testing program as follows: (aa) The TSH result that had been reported was 4.91, which was the calculated average of the result obtained from the 02:31 pm testing (4.78) and the result obtained from the 02:37 pm testing (5.04); (bb) The Free T4 result that had been reported was 2.9, which was the calculated average of the result obtained from the 02:14 pm testing (2.86) and the result obtained from the 02:21 pm testing (2.98). (3) The surveyor reviewed the records with the laboratory manager and asked for an explanation of the laboratory's method for testing proficiency testing samples, and if patient samples were tested in the same manner. The laboratory manager stated the following to the surveyor: (a) Proficiency testing samples were tested multiple times, with the mid-range result, first or last testing run, or an average of two testing runs used as the result reported to the proficiency testing program; (b) Patient specimens were routinely tested one time and not in the same manner the proficiency testing specimens had been tested.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to sign proficiency testing attestation statements. Findings include: (1) During the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records and identified attestation statements for 6 of 9 events had

	been signed by the laboratory manager (as designee) as follows: (a) First 2018 Hematology Event (b) Third 2018 Hematology Event (c) First 2019 Hematology Event (d) Second 2018 Chemistry Miscellaneous Event (e) Second 2018 Chemistry Core Event (f) Third 2018 Chemistry Core Event (2) The surveyor reviewed the personnel records for the laboratory manager and identified the laboratory manager earned a Bachelor of Science and met the qualifications of a technical consultant as required at 493.1409; (3) The surveyor asked the laboratory manager if the responsibility for signing the attestation statements had been delegated in writing by the laboratory director. The laboratory manager stated to the surveyor the laboratory director had not delegated in writing the responsibility for signing the attestation statements; (4) The surveyor explained to the laboratory manager since the responsibility for signing the attestation statements had not been delegated in writing, the laboratory director must sign the attestation statements. NOTE: The Interpretive Guidelines under D2015 state "For moderate complexity testing, in accordance with 493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of 493.1409."
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to verify the accuracy of urine microscopic testing at least twice annually. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed microscopic urine sediment examinations; (2) The surveyor reviewed proficiency testing records for 2018 and to date in 2019. The laboratory had not enrolled and participated in a proficiency testing program for urine microscopic testing; (3) Since the laboratory was not enrolled in proficiency testing (participation in a proficiency testing program is not required for microscopic urine sediment examinations; it is not a regulated test), the surveyor asked the laboratory manager to explain how the testing was verified for accuracy during 2018 and to date. The laboratory manager stated microscopic urine sediment examinations had not been verified for accuracy during 2018 and to date in 2019; (4) The following were examples of patient urine sediment examinations performed: (a) Patient #3 - Testing performed on 01/09/18 (b) Patient #4 - Testing performed on 01 /24/18 (c) Patient #5 - Testing performed on 02/16/18 (d) Patient #6 - Testing performed on 03/01/18 (e) Patient #7 - Testing performed on 04/04/18 (f) Patient #8 - Testing performed on 05/24/18 (g) Patient #9 - Testing performed on 06/03/18 (h) Patienet #10 - Testing performed on 07/19/18 (i) Patient #11 - Testing performed on 08/21/18 (j) Patient #12 - Testing performed on 09/26/18 (k) Patient #13 - Testing performed on 10/12/18 (l) Patient #14 - Testing performed on 11/20/18 (m) Patient #15 - Testing performed on 12/17/18 (n) Patient #16 - Testing performed on 01/21/19 (o) Patient #17 - Testing performed on 02/11/19 (p) Patient #18 - Testing performed on 03/12/19 (q) Patient #19 - Testing performed on 04/17/19 (r) Patient #20 - Testing performed on 05/15/19
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 a review of records, manufacturer's instructions, policies and procedures, observation, and interview with the laboratory manager, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed. Findings include: (1) The laboratory failed to ensure materials were stored as required. Refer to D5413; (2) The laboratory failed to have a function check protocol for ensuring the urine centrifuge was functioning properly. Refer to D5435; (3) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Refer to D5441; (4) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (5) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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 a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required. Findings include: (1) During the survey, the surveyor observed the contents of the Roper freezer in the laboratory phlebotomy room (designated by the laboratory as Room 2). The freezer was a frost free freezer. The following materials were being stored in the freezer, along with the manufacturer's storage requirements: (a) Access Free T4 Calibrators - 1 box (lot #831941) and 1 box (lot #832347); the storage requirement was -20 degrees Centigrade (C) and colder; (b) Access 25 (OH) Vitamin D Total Calibrator - 1 box (lot #832318); the storage requirement was -15 to -30 degrees C. (2) The laboratory manager explained to the surveyor the materials were used to perform calibration procedures for Free T4 and Vitamin D testing performed on the Beckman Coulter Access 2 analyzer; (3) The surveyor then reviewed laboratory temperature records from 05/01/18 through the day of the survey which verified temperature readings were documented as warmer than -20 degrees C (the warmest temperature to allow for both of the calibrators stored together) 12 of 12 months as follows: (a) May 2018 - 12 of 22 temperature readings were documented as warmer than -20 C (days 01,02,03,04,09,11,14,15,16,18,22,24) (b) June 2018 - 15 of 20 temperature readings were documented as warmer than -20 C (days 01,04,05,06,07,08,11,12,14,15,25,26 ,27,28,29) (c) July 2018 - 18 of 21 temperature

	readings were documented as warmer than -20 C (days 02,03,05,06,09,10,11,12,13,16,17,18,19,20,26,27,30,31) (d) August 2018 - 22 of 23 temperature readings were documented as warmer than -20 C (days 01,02,03,06,07,08,09,10,13,14,15,16,20,21,22,23,24,27,28,29,30,31) (e) September 2018 - 17 of 19 temperature readings were documented as warmer than -20 C (days 04,05,06,07,10,11,12,13,14,19,20,21,24,25,26,27,28) (f) October 2018 - 24 of 24 temperature readings were documented as warmer than -20 C (days 01,02,03,04,05,08,09,10,11,12,15,16,17,18,19,20,22,23,24,25,26,29,30,31) (g) November 2018 - 20 of 20 temperature readings were documented as warmer than -20 C (days 01,02,05,06,07,08,09,12,13,14,15,16,19,20,21,26,27,28,29,30) (h) December 2018 - 18 of 18 temperature readings were documented as warmer than -20 C (days 03,04,05,06,07,10,11,12,13,14,17,18,19,20,21,26,27,28) (i) January 2019 - 22 of 22 temperature readings were documented as warmer than -20 C (days 02,03,04,07,08,09,10,11,14,15,16,17,18,21,22,23,24,25,28,29,30,31) (j) February 2019 - 21 of 21 temperature readings were documented as warmer than -20 C (days 01,04,05,06,07,08,11,12,13,14,15,16,18,19,20,21,22,25,26,27,28) (k) March 2019 - 21 of 21 temperature readings were documented as warmer than -20 C (days 01,04,05,06,07,08,11,12,13,14,15,18,19,20,21,22,25,26,27,28,29) (l) April 2019 - 22 of 22 temperature readings were documented as warmer than -20 C (days 01,02,03,04,05,08,09,10,11,12,15,16,17,18,19,22,23,24,25,26,29,30) (m) May 2019 - 17 of 17 temperature readings were documented as warmer than -20 C (days 01,02,03,06,07,08,09,10,13,14,15,16,17,20,21,22,23) (4) The surveyor reviewed the records with the laboratory manager who stated the temperature of the freezer had not been maintained as required by the manufacturer of the calibrators.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to have a function check protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor urine sediment examinations were performed in the laboratory. The specimens were processed in the LW Scientific Ultra Select centrifuge at a speed of 1800 rpm (revolutions per minute) for 5 minutes; (2) The surveyor asked the laboratory manager if the laboratory had a written protocol defining the frequency the centrifuge speed and timer were to be checked and the criteria for acceptability. The laboratory manager stated to the surveyor a detailed protocol had not been written and showed the surveyor a statement contained in the "Laboratory Procedure Manual" which stated,"The centrifuge is calibrated annually by an outside service"; (3) The surveyor requested centrifuge records from 2017 through the current date. The laboratory manager stated to the surveyor centrifuge records could not be located and a sticker on the centrifuge was

	the only documented centrifuge check to date. The surveyor observed the sticker which indicated the centrifuge speed had been checked on 04/01/19 at 1800 rpm. There was no documentation the timer had been checked for accuracy; (4) The surveyor reviewed the findings with the laboratory manager who stated: (a) The laboratory did not have a written protocol for ensuring the urine centrifuge was functioning properly (including criteria of acceptability for the speed and timer checks); (b) There was no documentation timer checks had been performed from 2017 through the day of the survey; (c) There was no documentation speed checks had been performed prior to the one performed 04/04/19. (5) Refer to D5217 for examples of patient urine sediment examinations performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Findings include: (1) At the beginning of the survey, the laboratory manager stated the following to the surveyor: (a) PSA (Prostate Specific Antigen), Testosterone, Vitamin D, TSH (Thyroid Stimulating Hormone), and Free T4 testing were performed using the Beckman Coulter Access 2 analyzer; (b) Three levels of Thermo Scientific MAS Omni-Immune Liquid Assayed Integrated Immunoassay control materials were tested as follows: (i) Level 1 was tested each day of patient testing, with level 2 and level 3 alternated every other day. (2) Later during the survey, the surveyor reviewed quality control records for 3 lot numbers of control materials used from 09/04/18 through the day of the survey. For 3 of 3 lot numbers (level 1 lot #OIM2010-1, level 2 lot #OIM2010-2, and level 3 lot #OIM2010-3), there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances; (3) The surveyor asked the laboratory manager if the lot numbers above had been monitored for variances. The laboratory manager stated to the surveyor the controls were not routinely monitored for variances; (4) The following were examples of patient testing performed when the laboratory had not monitored QC results for variances: (a) Patient #21 - PSA and Testosterone testing performed 09/04/18 (b) Patient #22 - Free T4 and TSH testing performed on 09/04/18 (c) Patient #23 - Vitamin D testing performed on 09/10/18 (d) Patient #24 - Free T4, TSH, Testosterone, and Vitamin D testing performed on 09/13/18 (e) Patient #25 - Free T4 and TSH testing performed on 09/18/18 (f) Patient #26 - TSH, PSA, and Testosterone testing performed on 09/20/18 (g) Patient #27 - PSA and Tsetosterone testing performed on 09/24/18 (h) Patient #28 - Free T4, TSH, and PSA testing performed on 09/27/18 (i) Patient #29 - TSH and Vitamin D testing performed on 10 /01/18 (j) Patient #30 - PSA testing performed on 10/10/18 (k) Patient #31 - Free T4

	and TSH testing performed on 10/15/18 (l) Patient #32 - Free T4, FSH, Testosterone testing performed on 10/23/18 (m) Patient #33 - PSA and Testosterone testing performed on 10/25/18 (n) Patient #34 - Free T4, TSH, and Vitamin D testing performed on 10/29/18 (o) Patient #35 - Vitamin D testing performed on 01/02/19 (p) Patient #36 - Free T4 and TSH testing performed on 01/02/19 (q) Patient #37 - TSH and Vitamin D testing performed on 01/07/19 (r) Patient #38 - Free T4, TSH, and Vitamin D testing performed on 01/11/19 (s) Patient #39 - TSH and PSA testing performed on 01/15/19 (t) Patient #40 - Vitamin D testing performed on 01/17/19 (u) Patient #41 - TSH and Testosterone testing performed on 01/21/19 (v) Patient #42 - Free T4 and TSH testing performed on 01/23/19 (w) Patient #43 - PSA and Testosterone testing performed on 01/28/19 (x) Patient #44 - Vitamin D testing performed on 04/01/19 (y) Patient #45 - TSH and PSA testing performed on 04/01/19 (z) Patient #46 - Testosterone testing perforned on 04/01/19 (aa) Patient #47 - Free T4 and TSH testing perforned on 04/01/19 (bb) Patient #48 - Free T4, TSH, and Vitamin D testing perforned on 04/02/19 (cc) Patient #49 - Free T4 and TSH testing perforned on 04/03/19 (dd) Patient #50 - Testosterone and Vitamin D testing performed on 04/11 /19 (ee) Patient #51 - Free T4, TSH, and PSA testing perforned on 04/11/19 (ff) Patient #52 - Free T4, TSH, PSA, and Vitamin testing perforned on 04/12/19 (gg) Patient #53 - PSA and Testosterone testing perforned on 05/01/19 (hh) Patient #54 - TSH and Vitamin D testing performed on 05/01/19 (ii) Patient #55 - PSA, Testosterone, and Vitamin D testing perforned on 05/07/19 (jj) Patient #56 - TSH and Vitamin D testing perforned on 05/13/19 (kk) Patient #57 - Free T4, TSH, PSA, and Testosterone testing perforned on 05/22/19
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) At the beginning of the survey, the laboratory manager stated the following to the surveyor: (a) PSA (Prostate Specific Antigen), Testosterone, Vitamin D, TSH (Thyroid Stimulating Hormone), and Free T4 testing were performed using the Beckman Coulter Access 2 analyzer; (b) Three levels of Thermo Scientific MAS Omni-Immune Liquid Assayed Integrated Immunoassay control materials were tested as follows: (i) Level 1 was tested each day of patient testing, with level 2 and level 3 alternated every other day. (2) Later during the survey, the surveyor reviewed the manufacturer's instructions for the control materials which stated, "Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges."; (3) The surveyor then reviewed quality control records for the current lot numbers of control materials (level 1 lot #OIM2010-1, level 2 lot #OIM2010-2, and level 3 lot #OIM2010-3) used for patient testing from 09/04/18 through the day of the survey, with the laboratory manager. The laboratory manager stated the laboratory had used the package insert means and limits for each level of control instead of establishing

	their own means and limits as stated in the manufacturer's package insert; (4) Refer to D5441 for examples of patient testing performed when the laboratory failed to establish quality control means and limits.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to ensure materials were stored as required. Refer to D5413; (b) The laboratory failed to have a function check protocol for ensuring the urine centrifuge was functioning properly. Refer to D5435; (c) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Refer to D5441; (d) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to make appropriate reference ranges available. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex pocH-100i analyzer; (2) Later during the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male (patient #1) with the testing performed on 05/22 /19 at 03:02 pm; the second report was for an adult female (patient #2) with the testing performed on 05/23/19 at 12:51 pm. Both reports included the same reference intervals for the CBC parameter of RBC (Red Blood Cell) which was: (a) RBC - 4.04 - 6.13 (1000000/ul) (3) The surveyor reviewed the findings with the laboratory manager, who stated the patient reports did not include gender specific reference ranges for RBC. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
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 a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Refer to D6016; (3) The laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems requiring corrective action. Refer to D6018; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory failed to ensure materials were stored as required. Refer to D5413; (2) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479.
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 records and interview with the laboratory manager, the laboratory director failed to ensure proficiency testing samples were tested as required

	under Subpart H. Findings include: (1) The laboratory director failed to ensure that proficiency testing samples were tested by personnel who routinely performed patient testing. Refer to D2007; (2) The laboratory director failed to ensure proficiency testing samples were tested the same number of times that patient samples were tested. Refer to D2010.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems requiring corrective action. Findings include: (1) The laboratory director failed to sign proficiency testing attestation statements. Refer to D2015;
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 a review of records, policies and procedures, and interview with the laboratory manager, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the accuracy of urine microscopic testing was verified at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure there was a function check protocol for ensuring the urine centrifuge was functioning properly. Refer to D5435; (3) The laboratory director failed to ensure control procedures monitored the accuracy and precision of the testing process. Refer to D5441.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D5807.