Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114136	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
United Bioscience, Llc	901 W Leuda St Suite B, Fort Worth, 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	An unannounced investigation of complaint TX00328018 was conducted on 10/22 /2019. This facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1441 Laboratory Director 493.1447 Laboratory Technical Supervisor Complaint TX00328018 was substantiated. An exit conference was held on 10/22/2019 with the testing person. The exit conference attendee was advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. On 10 /24/2019, the laboratory owner provided documentation that the laboratory has ceased testing. ---------- 493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This STANDARD is not met as evidenced by: Based on review of electronic mail (email) documents and in telephone interview with the laboratory owner, the laboratory failed to notify the State Agency (SA) within 30 days of change in ownership (change occurred 04/18/2019). Findings included: 1. On 10/17/2019 at 2:32 pm, the SA received an email from United Bioscience previous owner stating, "Thank you for your recent email communications. Please note that United Bioscience LLC with CLIA #45D2114136 has transferred ownership earlier in 2019, specifically on April 18, 2019. We are not sure that the new owner provided notice to your CLIA office, however we would ask that you direct any future correspondence to the following contact (new owner): [company name, new owner name, address, telephone number and email address]. [testing person name] should still be reachable at the laboratory as well." The SA replied on 10/18/2018 at 9:38 am, asking, "I see there is a Utah

	address, has the CLIA number moved to Utah or is there an address in the DFW area?" On 10/18/2019 at 1:02 pm, the previous owner replied stating, "The only DFW area local address that we know of is the lab address - 901 W Leuda Suite B, Fort Worth, Texas 76104. Regarding the question about moving the CLIA to Utah, I would have no knowledge of that since we have very limited communication with the new owners. It would be best to direct that question to them directly, contact info and email below in last email." The SA had never receive notification of the change in ownership with a CMS 116 application (effective 04/18/2019), within the required 30 days. The SA was made aware of the change by the previous owner 6 months later on 10/17/2019 via email. 2. During a telephone interview on 10/22/19 at 11:33 a.m., the new laboratory owner, stated that he had purchased the laboratory in 04/2019. He stated that he thought the change in ownership had been submitted to the state agency. This confirmed the above findings.
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 review of electronic mail (email) documents, verification records, patient requisitions, patient test reports, and in interview with staff, the laboratory did not have a laboratory director to provide overall management and direction, as required. The laboratory failed to ensure a laboratory director was employed to provide oversight when patient testing occurred from 06/25/2019 through 09/30/2019 (total of 31 patients).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high

complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
Based on review of email documents, verification records, patient requisitions, patient test reports, and in interview with staff, the laboratory failed to ensure a laboratory director was employed to provide oversight when patient testing occurred from 06/25 /2019 through 09/30/2019 (total of 31 patients). Findings included: 1. On 10/05/2019 at 9:23 am, the SA received an email from the laboratory director, stating, "This is to inform you that I have resigned from United Bioscience laboratory effective April 16 2019 [sic]. I no longer work there and would like CLIA to make a note of the same. Please direct all future communication to [testing person name] at United Bioscience." 2. On 10/07/2019 at 10:49 am, the SA sent an email to the testing person, stating, "We received notification from the lab director that they resigned in April. Please submit a CMS 116 form with the current lab director." The SA never received a response and did not receive a CMS 116 application designating the new laboratory director. 3. On 10/18/2019 at 9:33 am, the SA sent an email to the new owner (effective date 04/18 /19) stating, "I was given your contact [previous owner name] former owner of United BioScience. He stated that Aperture Medical, LLC purchased United BioScience 45D2114136 on April 18, 2019. Please call me as soon as possible to discuss this matter. My office number is below." The SA never received a response and did not receive a CMS 116 application designating the new laboratory director. On 10/21 /2019 at 9:38 am, the SA sent a second email to the new owner, stating, "This is the second email attempt to reach you. I have called the number provided by [previous owner name] former owner of United Bioscience and have left two messages as well. Please return my call promptly. I have also called and emailed the laboratory. I have left messages as well with no return call or email." The SA never received a response and did not receive a CMS 116 application designating the new laboratory director. 4. During a telephone interview on 10/22/19 at 11:33 a.m., the new laboratory owner, stated that he had purchased the laboratory in 04/2019. He stated that the laboratory director was supposed to stay on as the laboratory director when the sale occurred. He stated that he found out on 10/07/2019 that the laboratory director had resigned on 04 /16/2019. He stated that the resignation date had been back dated by the laboratory director. He also stated that he has been trying to find a laboratory director to replace the previous laboratory director. He stated that facility has been running specimens from the previous owner's private practice. He stated that he planned to close the laboratory at the end of the month (10/2019). 5. During the onsite complaint investigation on 10/22/2019 at 2:00 pm, the testing person provided the surveyors documentation of emails exchanged between him and the laboratory director. Review of the email exchange was dated 06/21/2019 and included an attachment signed and dated (06/20/2019) by the laboratory director titled: "Laboratory Validation of a Quantitative Assay" (pH) for the Beckman Coulter AU480. The signed document was in a binder for "Beckman Coulter AU480 CEDIA and DRI DAU Assay Validation;

Validated by: [testing person name]; Title: Director of Lab Services; Date: Week of OCTOBER 08, 2018; Serial #: 20160140092; System ID: 24794335." The laboratory director had stated her last day was 04/16/2019, yet signed a verification study on 06 /20/2019. 6. Further review revealed the laboratory had been testing patient urine specimens for drugs of abuse and adulterants on the Beckman Coulter AU480 without a laboratory director. Review included patient test requisitions and final test reports from 06/25/2019 through 09/30/2019, as follows: Patient #190624001 specimen was collected 06/24/2019 and tested 06/25/2019 Patient #190624003 specimen was collected 06/24/2019 and tested 06/25/2019 Patient #190624002 specimen was collected 06/24/2019 and tested 06/25/2019 Patient #190628002 specimen was collected 06/26/2019 and tested 06/28/2019 Patient #190628004 specimen was collected 06/26/2019 and tested 06/28/2019 Patient #190628003 specimen was collected 06/26/2019 and tested 06/28/2019 Patient #190628005 specimen was collected 06/27/2019 and tested 06/28/2019 Patient #190628001 specimen was collected 06/28/2019 and tested 06/28/2019 Patient #190724001 specimen was collected 07/24/2019 and tested 07/25/2019 Patient #190730001 specimen was collected 07/29/2019 and tested 07/30/2019 Patient #190730002 specimen was collected 07/29/2019 and tested 07/30/2019 Patient #190805001 specimen was collected 07/31/2019 and tested 08/05/2019 Patient #190805003 specimen was collected 08/02/2019 and tested 08/05/2019 Patient #190805002 specimen was collected 08/02/2019 and tested 08/05/2019 Patient #190805004 specimen was collected 08/02/2019 and tested 08/05/2019 Patient #190806002 specimen was collected 08/05/2019 and tested 08/06/2019 Patient #190806001 specimen was collected 08/05/2019 and tested 08/06/2019 Patient #190830003 specimen was collected 08/28/2019 and tested 08/30/2019 Patient #190830002 specimen was collected 08/28/2019 and tested 08/30/2019 Patient #190830001 specimen was collected 08/29/2019 and tested 08/30/2019 Patient #190830004 specimen was collected 08/29/2019 and tested 08/30/2019 Patient #190903003 specimen was collected 08/30/2019 and tested 09/04/2019 Patient #190903002 specimen was collected 08/30/2019 and tested 09/04/2019 Patient #190903001 specimen was collected 08/30/2019 and tested 09/04/2019 Patient #190927002 specimen was collected 09/24/2019 and tested 09/27/2019 Patient #190927001 specimen was collected 09/24/2019 and tested 09/27/2019 Patient #190927005 specimen was collected 09/25/2019 and tested 09/27/2019 Patient #190927004 specimen was collected 09/26/2019 and tested 09/27/2019 Patient #190927003 specimen was collected 09/26/2019 and tested 09/27/2019 Patient #190930002 specimen was collected 09/27/2019 and tested 09/30/2019 Patient #190930001 specimen was collected 09/27/2019 and tested 09/30/2019 The patients mentioned above were all tested for: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cannabinoids (THC), Cocaine, Ecstasy (MDMA), Ethyl Alcohol, Methadone, Opiates, Oxycodone, Phencyclidine (PCP), Propoxyphene, and adulterants pH, Oxidants, and Creatinine. 6. During an interview on 10/22/19 at 2:00 p.m., the testing person, stated that the last time he had any communication with the laboratory director was on 06/21/2019 when she returned a signed verification study via email. He stated that he had attempted to contact the laboratory director via phone and text messages on numerous occasions and she was not returning any messages. He stated that the change in ownership occurred in April or May of 2019 and he did not have any of those documents. He stated that he found out about the laboratory director's resignation when the state agency contacted him to ask about her resignation on 10/07 /2019. He stated that he contacted the new owner via email to inform him of her resignation. He stated that the laboratory has been testing urine toxicology specimens. The last specimens received in the laboratory for testing was on 09/30/2019. He stated that to his knowledge the laboratory director never submitted a letter of resignation. 7.

	On 10/22/2019 at 5:21 pm, the SA sent an email to the laboratory director asking, " Do you have any documentation (email/letter, etc.) of your resignation to the previous or new owner?" There was no reply. On 10/24/2019 at 3:55 pm, the SA sent a second email to the laboratory director stating, "We are trying to obtain an accurate date of your resignation. We have documentation from United Bioscience that includes an email exchange between you and the testing person for signing a verification study on 06/21/19 and the pH verification document with your signature/date from 06/20/19 (see attachments). In order to determine the action that will be taken on the laboratory, an accurate date is essential. If you have something in writing that was provided to the lab about your resignation that would be helpful or a more accurate date. Thank you, ..." On 11/18/2019 at 9:59 am, the laboratory director replied via email, stating, "My apologies for the delay in response as I was out of country due to...Attached is the letter of resignation. I have effectively resigned April 16th, 2019 from United Biosciences Lab. I have received no salary since or after that date. As for the letter on 6/20/19. That was just done as a courtesy to help the previous owners of United Biosciences out for that one last time. I have had no communication after that or intend having any more contact with the laboratory." The letter attached to the email stated, "Dear [previous owner name], As per our verbal conversation, I am unable to work as Medical Director of United Bioscience due to...This letter is to confirm my resignation effective April 16th 2019 ..." The laboratory director was involved with the laboratory until 06/21/2019 based on signed/approved verification studies cleared for testing (a laboratory director responsibility). The laboratory did not ensure a laboratory director was employed to provide oversight when patient testing occurred from 06/25/2019 through 09/30/2019.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS 209 from the initial survey, personnel records, email documentation, and in interview with staff, the laboratory did not have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision. The laboratory did not employ a technical supervisor (TS) who meets qualifications to provide technical oversight of high complexity testing, as required by a directed plan of correction. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to

those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6

months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum

of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or

osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American

Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each

specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's CMS 209 from the initial survey, personnel records, email documentation, and in interview with staff, the laboratory did not employ a technical supervisor (TS) who meets qualifications to provide technical oversight of high complexity testing, as required by a directed plan of correction. Findings included: 1. On 12/17/2018 through 12/19/2018, an initial survey was conducted and review of the CMS 209 form included one individual listed as the TS for providing oversight of high complexity testing (urine drug screen testing performed on AU480 analyzer and allergy testing performed on Hitachi CLA-1). 2. Personnel records for individual listed as TS revealed educational documents did not meet the qualifications for serving as a TS. The listed TS education included a diploma for a bachelor of science in agriculture. The listed TS provided additional transcripts that included completed science classes but no completion of degrees. The individual did not meet the educational requirements for a TS: have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution. The laboratory was cited for the Technical Supervisor condition deficiency. 3. On 04/16/2019, the SA sent the CMS-2567 for the 12/19 /2018 survey to the laboratory. On 04/26/2019, the plan of correction (POC) was submitted by the laboratory and received by the SA for review. On 05/22/2019, the SA reviewed the POC and notified the laboratory it was unacceptable. On 05/31/2019, the POC was submitted by the laboratory and received by the SA for review, which was found to be unacceptable. On 06/03/2019, the Regional Office was notified of the laboratory's unacceptable POC's and the SA requested a Directed Plan of Correction (DPOC). The DPOC was to require the laboratory to hire a qualified TS and provide an acceptable POC. On 10/03/2019, the Regional Office emailed an enforcement letter with a DPOC and CMS 2567 report to the laboratory (testing person). On 10/03 /2019, the testing person who received the enforcement letter with a DPOC and CMS 2567 report forwarded it via email to the laboratory director (see attached email documents). The SA never received a response from the laboratory with an acceptable POC. 4. During a phone interview on 10/22/19 at 11:33 am, the laboratory owner, stated that he had purchased the laboratory on 04/2019. He stated that he did not know the "technical supervisor" did not qualify. He stated that the "technical supervisor" was working on getting a certification and letters of recommendations in order to qualify as a technical consultant/supervisor. (Note: a change of ownership notification /documentation was never submitted by the new owner to the SA) 5. The SA never received an acceptable POC and never received documentation of a qualified TS. The laboratory continued operating until 09/30/2019 for urine drug screens.