

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1093662	(X3) Date Survey Completed 02/21/2018
Name of Provider or Supplier Integrated Health Concepts, Llc	Street Address, City, State 1615 Bluff City Hwy, Bristol, TN	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: _____ Based on observation of microscope and centrifuge during lab tour for performing Urine Microscopics, lack of procedure for Urine Microscopic Analysis and interview with the Laboratory Technician, determined there was no procedure in place for performing Urine Microscopics since testing began in 2017. The findings include: 1. Observation during lab tour at approximately 10:00 a.m. February 21, 2018 of microscope and centrifuge used for performing Urine Microscopics. 2. Lack of procedure to include requirements as listed under CLIA for performance of Urine Microscopic Analysis and centrifuge spin</p>

speed and time since testing began in 2017. 3. Interview at approximately 10:00 a.m. February 21, 2018 confirmed that Urine Microscopic testing began in 2017 and there was no procedure in place prior to patient testing to ensure integrity of patient testing.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

_____ Based on review of four patient reports in 2017 which lacked testing person's identification and interview with the Laboratory Technician, determined the laboratory reports do not include identity of testing person. The findings include: 1. Review of four patient reports dated 1/25/17; 4/18/17; 8/24/17 and 11/28/17 lacked testing person's identification for all reports reviewed. 3. Interview at approximately 4:00 p.m. February 21, 2018 with Laboratory Technician confirmed the laboratory reports did not and do not include identity of testing person.

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:

_____ The Laboratory Director failed to fulfill the laboratory director's responsibilities (reference D6016, D6018, D6029, D6031).

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 review of Proficiency Testing (PT) records for 2017, lack of director and testing person attestation signatures and

interview with laboratory technician and laboratory director, determined the laboratory director failed to ensure PT samples were tested as required by Subpart H by lack of attestation signatures. The findings include: 1. Review of PT records for 2017 revealed attestation sheets for hematology, chemistry and immunoassay testing for 3 of 3 events were not signed by lab director and 2 of 2 events were not signed by testing person. 2. Interview at approximately 2:30 p.m. February 21, 2018 with the laboratory technician and laboratory director confirmed that attestation sheets for 2017 were not signed. _____

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 review of Proficiency Testing (PT) program evaluation reports for 2017 which lacked director review and corrective action documentation and interview with the laboratory technician and laboratory director, determined the laboratory director failed to ensure review and evaluation of proficiency testing results for 2017. The findings include: 1. Review of PT evaluation reports for 2017 revealed the following: a. The 1st event for Hematology had unacceptable results for the WBC (white blood cell) Auto Differential with no corrective action documented and no review by the laboratory director. b. The 2nd event for Chemistry lacked review by laboratory director. c. The 1st event for Endocrinology had unacceptable results for DHEA-S and no review by laboratory director. d. The 1st event for Chemistry failed to be reported in time which received 0% scores, lacked review by director. e. The 3rd event for Hematology failed to be reported in time which received 0% scores, lacked review by director. 2. Interview at approximately 2:00 p.m. February 21, 2018 with laboratory technician and laboratory director confirmed the director failed to ensure review and evaluation of Proficiency Testing results for 2017. _____

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

_____ Based on lack of training and competency documentation for review since October 2016 for Medical Laboratory Technician (MLT-the only testing person) and interview with the Medical Laboratory Technician and Laboratory Director, determined the Laboratory Director failed to ensure the MLT had the appropriate training documented for all laboratory services offered to include Chemistry, Endocrinology, Hematology and Urinalysis since hire date in October of 2016. The findings include: 1. There was no training and/or competency documentation for review for the only testing person (MLT) hired in October 2016 for services offered to include Chemistry, Endocrinology, Hematology and Urinalysis. 2. Interview at approximately 2:00 p.m. February 21, 2018 with the MLT and Laboratory Director confirmed there was no documentation of training and competency on file for the only testing person hired in October 2016.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

_____ Based on lack of procedure for Urine Microscopics and interview with the Laboratory Technician, determined the Laboratory Director failed to ensure an approved procedure for performing Urine Microscopics was in place since testing began in 2017. The findings include: 1. Lack of procedure for performing Urine Microscopics since testing began in 2017. 2. Interview at approximately 4:00 p.m. February 21, 2018 with the Laboratory Technician confirmed there was no procedure in place for performing Urine Microscopics since 2017. _____