

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2064227	(X3) Date Survey Completed 10/30/2019
Name of Provider or Supplier Convenientmd, Llc	Street Address, City, State 8 Loudon Rd, Concord, NH	
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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the stated values for 2 of 5 lot numbers of assayed control material used for hematology testing from February 2019 to October 2019. Findings include: 1) Review on 10/30/2019 of control records for complete blood count (CBC) from 2/1/19 to 10/30/19 revealed the laboratory has used 5 lot numbers for CBC controls during this period. The current lot number (92810710, 92810711, 92810712 expiration 1/15/20) was put into use on 10/24/2019 and was not run for verification prior to 10/24/19. The previous lot number (91970710, 91970711, 91970712 expiration 10/23/2019) was put into use on 8/2/2019 and had not been run for verification prior 8/2/19. 2) Interview on 10/30/2019 at 12:30 p.m. with testing personnel (TP2) confirmed the above finding.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant (TC) failed to evaluate and document competency assessments semiannually for 5 of 5 testing personnel performing hematology testing who were hired (and trained) in 2017, 2018. This is a repeat deficiency from the recertification survey completed on 11/20/2017. Findings include: 1) Review on 10/30/2019 of 5 testing personnel (TP) records revealed the following: TP3 completed training for complete blood counts (CBC) in May 2018, there was no documentation for semiannual evaluations of CBC performance in the first year. TP4 records did not include documentation of training or evaluations of performance semiannually with the first year for CBCs. TP5 completed CBC training in November 2017, the first evaluation was performed in May 2018, there was no documentation of a second evaluation within the personnel's first year of performing CBCs. TP6 completed CBC training in January 2018, the first evaluation was performed in July 2018, there was no documentation of a second evaluation for CBC performance in the first year. TP7 completed CBC training in November 2017, the first evaluation of CBC performance was performed in May 2018, there was no documentation of a second evaluation for CBC performance in the first year. 2) Interview on 10/30/2019 at 10:30 a.m. with the laboratory Director (LD) revealed the competency assessments missing from the above personnel records had not been performed. 3) Interview on 10/30/2019 at 11:45 a.m. with testing personnel (TP2) revealed TP4 had been trained for CBC testing in April 2018. TP2 confirmed the training documentation was not in TP4's personnel record.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant failed to evaluate and document performance for hematology testing annually for 3 of 3 testing personnel (TP) in 2019. Findings include: 1) Review on 10/30/2019 of 3 personnel records revealed no documentation for annual competency assessments for TP5, TP7, and TP8 in 2019. 2) Interview on 10/30/2019 at 10:30 a.m. with the laboratory director revealed the competency assessments for the above personnel had not been performed in 2019.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review and staff interview, 1 of 7 new laboratory personnel hired between 2017 to 2019 failed to meet educational qualifications for testing personnel performing moderate complexity testing. Refer to tag D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and staff interview, 1 of 7 new laboratory personnel hired 2017 to 2019 failed to meet educational qualifications for testing personnel performing moderately complex hematology testing. Findings include: 1) Review on 10/30/2019 of Form HCFA-209, Laboratory Personnel Report (CLIA), revealed 7 new testing personnel. 2) Review on 10/30/2019 of personnel records revealed the record for 1 (TP1) of 7 new testing personnel failed to include documentation of educational qualifications. Further review of TP1's personnel record revealed the tracking system used upon hiring stated the documentation for TP1's education had not been received. TP1 was hired in July 2019 and completed training for complete blood cell (CBC) testing in August 2019. 3) Interview on 10/30/2019 at 12:20 p.m. with the laboratory director (LD) confirmed the laboratory did not obtain documentation of educational qualifications for TP1 and TP1 performed CBC testing. The LD revealed it is the responsibility of the laboratory's human resource department to ensure new hires meet qualification requirements and to review personnel records for completeness.