

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1100036	(X3) Date Survey Completed 08/17/2018
Name of Provider or Supplier Topcare Medical Group Inc	Street Address, City, State 410 E Pioneer Pkwy Suite 300, Grand Prairie, 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 entrance conference was held 08/17/2018 with Technical Consultants #1 and #2. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 08/17/2018, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties /subspecialties in which it was surveyed. 493.1421 Laboratory Testing Personnel (moderate complexity) An exit conference was held on 08/17/2018 with Technical Consultants #1 and #2. The exit conference attendee was advised the laboratory was out of compliance and advised of condition and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, quality control records for Qualigen, patient test results and in interview with staff, the laboratory failed to ensure their quality assessment (QA) program included a review of effectiveness of corrective action taken to resolve problems when identified in analytic systems. Findings included: 1. Review of the laboratory's policy stated, "QUALITY CONTROL POLICY: 2. When one of both levels of QC fails, the first step is to repeat the control which exceeded acceptable limits...Record the problem and the corrective action.. 4. When a QC failure occurs, patient reports released since the last acceptable test run must be evaluated to determine if there is significant clinical difference in patient results...Quality control records will be evaluated monthly for trends and/or shifts." 2.</p>

Review of Thyroid Stimulating Hormone (TSH) Qualigen QC results log from 01/2017 revealed one level of TSH QC was not acceptable and patients were analyzed: 01/04/2017 - Level 2 (Lot #1605002) result was 10.4 (acceptable range: 19.9 - 35.9) and 8 patients were tested for TSH (Patient #369748, Patient #412108, Patient #45473, Patient #446325, Patient #76473, Patient #803869, Patient #340038, Patient #605534). 01/03/2017 was the last acceptable QC run and there were 3 patients tested for TSH (Patient #136948, Patient #803576, Patient #801523). 3. On the "TSH DAILY QC RESULTS QUALIGEN" log, there was documentation by Technical Consultant #2 that stated, "Call back pts (patients)" on the 01/04/2017 QC results. Only 1 of the 8 patients from 01/04/2017 was recollected and repeated at a later date. For 10 of the 11 patients (01/03/2017 and 01/04/2017), there was no documentation of evaluation to determine if results were affected. The laboratory's QA system did not include a review of effectiveness for problems identified in analytic systems. 4. During an interview on 08/17/2018 at 11:30 am, Technical Consultants #1 and #2 reviewed and confirmed the above findings.

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 review of the CMS 209 form, personnel records and in interview with staff, the laboratory failed to ensure testing persons met qualification requirements to perform functions in moderate complexity testing. The laboratory failed to ensure 1 of 5 Testing Persons (TP-3) met requirements to perform moderate complexity testing (hematology and endocrinology). Refer to 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 review of the CMS 209 form, personnel records and in interview with staff, the laboratory failed to ensure 1 of 5 Testing Persons (TP-3) met requirements to perform moderate complexity testing (hematology and endocrinology). Findings included: 1. Review of the CMS 209 form included TP-3 listed to perform moderate complexity testing, which included hematology (Act Diff 2) and endocrinology

(Thyroid testing on Qualigen) procedures. 2. Review of personnel records for TP-3 revealed a U.S. equivalency for Doctor of Medicine. TP-3 records did not include a license to practice medicine in Texas and did not include any other U.S. equivalency for a doctoral, master's, bachelor's or associate's in a chemical, physical, biological or clinical laboratory science (or high school diploma). TP-3 did not meet one of the requirements to be able to perform moderate complexity testing. 3. During an interview on 08/17/2018 at 9:30 am, Technical Consultant #1 and #2 confirmed the above findings.