PCP:	Page 1 of 2
SECTION: Clinical Services	
POLICY AND PROCEDURE: Laboratory Services	Approved date: _____ Approved by: _____ Effective date: _____ Revised date: _____ Revised date: _____

POLICY:
The site will operate in compliance with Clinical Laboratory Improvement Amendment (CLIA) regulations. Therefore, the site shall meet all quality standards to ensure accuracy, reliability and timeliness of patient test results. All lab results are to be communicated to the provider and member in a timely manner.

PROCEDURE:

A. Laboratory test procedures are performed according to current site-specific CLIA certificate.

1. All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease, have a current, unrevoked, unsuspended site-specific Clinical Laboratory Improvement Amendment (CLIA) certificate, or evidence of renewal.
   - The CLIA Certificate on site includes one of the following:
     a. Certificate of Waiver: Site is able to perform only exempt waived tests, so therefore, has a current CLIA Certificate or Waiver. The current listing of waived tests may be obtained at www.fda.gov/cdrh/clia/testswaived.html.
        - There are no specific CLIA regulations regarding the performance of waived tests. Therefore, site personnel are expected to follow the manufacturer's instructions.
        - Laboratories with Certificates of Waiver may not be routinely inspected by DHCS Laboratory Field Services Division, but may be inspected as part of complaint investigations and/or on a random basis to determine whether only waived tests are being performed.
     b. Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists or mid-level practitioners are able to perform PPM procedures and waived tests.
     c. Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations is determined by survey.
        - For moderate and/or high complexity lab testing, the CLIA regulations list specific requirements for laboratory proficiency testing, patient test management, quality control, quality assurance, personnel and inspections.

d. Certificate of Compliance: Lab has been surveyed and found to be in compliance with all applicable CLIA requirements.
e. Certificate of Accreditation: Lab is accredited by an accreditation organization approved by the Centers for Medicare & Medicaid Services (CMS).

2. CLIA certification/re-certification includes an evaluation every two years (or sooner, if complaint driven) by DHCS of personnel licenses/training, laboratory site inspection and demonstration of testing proficiency for moderate and high-complexity test sites.

B. Testing personnel performing clinical lab procedures have been trained.

1. Prior to testing biological specimens, personnel are appropriately trained for the type and complexity of the laboratory services performed. Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately.
2. Site personnel that perform CLIA waived tests have access to and are able to follow test manufacturer's instructions.
3. When requested, site personnel are able to provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.
4. The required training and certification is established by legislation (CA B&P Codes, §1200-1213) for personnel performing moderate and high complexity tests. Reviewers are not expected to complete an in-depth evaluation of personnel performing moderate and high complexity tests.

C. Lab supplies are inaccessible to unauthorized persons.

D. Lab test supplies (e.g., vacutainers, culture swabs, test solutions) are not expired. Site has procedure to check expiration date and a method to dispose of expired lab test supplies.

E. The provider will review, initial and date the original copy of each laboratory report, which is then filed in member's medical record.

****For questions regarding CLIA certification, laboratory licensing, and personnel:**
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html