Methodist Health Services Corporation & UnityPoint Health Methodist|Proctor	Page # 1 of 3	Section: UPPIA LA Regulatory & Administrative	Policy #: 02.004 Formally: B-04
	Approved by: see signature block at end of document		Date: 9/12/16
Laboratory Administration	Date Revised: Supersedes, 9/12/16, 1/27/16, 6/1/12,1/5/96, 6/19/00, 1/8/03,4/19/06, 9/1/08, 6/22/10, 7/11/11 Date Reviewed: 3/10/14		
	Policy/Revision Submitted by: Richard Borge		
	CAP Standard: NA		

POLICY GUIDELINE ON: **Patient Test Management for High Complexity Testing**

I. POLICY:

Patient test management in our laboratory should include those items in the following procedure.

II. PURPOSE:

To identify and clarify those standards that must adhere to satisfy Subpart J of the CLIA regulations.

III. POLICY SCOPE:

The scope of this policy applies to all Laboratory Staff at both campuses.

IV. GENERAL INFORMATION:

A. Each laboratory performing high complexity testing must employ and maintain a system that provides for proper patient preparation, proper specimen collection, identification, preservation, transportation, processing, and accurate result reporting.
   1. This system must assure optimum patient specimen integrity and positive identification throughout the pre-testing, testing, and post-testing processes.
   2. If a test order is unclear and/or the requested test is no longer available the ordering provider must be contacted for clarification prior to order entry.

B. In addition, storage of records should be in a manner that allows for easy access in the event of an inspection or legal action.

V. PROCEDURE:

A. Procedures for specimen submission and handling
   1. The laboratory must have available and follow written procedures and policies for each of the following if applicable:
      a. methods used for the preparation of the patients
      b. specimen collection
      c. specimen labeling
      d. specimen preservation
      e. conditions for specimen transportation
      f. For the Department of Pathology and Laboratory Medicine at Methodist Medical Center, this information is found in the User's Manual, and is also available online.

   2. If the laboratory accepts referral specimens, written instructions must be available to clients and must include the information specified in 1.
      - The User's Manual contains this information.

   3. Oral explanation of instructions to patients for specimen collection including patient preparation may be used in lieu of written instructions.

B. Test requisitions
   1. The laboratory must perform tests only at the written or electronic request of the authorized person.
      a. Requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days.
      b. The requisitions must contain the patient's name or other unique identifier, the name and address or other suitable identifiers of the authorized persons requesting the test, test to be performed, the date of specimen collection; for pap smears - the patient's last menstrual period, age or date of birth and indication of whether the patient had a previous abnormal report, treatment, or biopsy, and any additional information relative and necessary to specific tests to assure accurate and timely testing and reporting of results.
      c. All requisitions must be retained for a minimum of ten years and must be available to the laboratory at the time of testing.
      d. These records will be stored on site or stored with a contracted storage company.

C. Test records
   1. The laboratory must maintain a record system to ensure reliable identification of patient's specimens as they are processed and tested to assure that accurate test results are reported.
      a. These records must identify the personnel performing the testing procedure.
         (i) Records of patient testing including quality control and, if applicable, instrument printouts must be retained for at least two years,
         (ii) Immunohematology records must be retained for no less than five years.
      b. Preventive maintenance records on instruments must be kept as long as the instrument is in use.
      c. These test records will be our worksheets, calibrations, and control information.

   2. These records must maintain the patient's identification number, accession number or other unique identification, the date and time the specimen was received in the laboratory which will be in the Laboratory Information system, the condition of the specimens that do not meet the laboratory's criteria or specimen acceptability, and the records and dates of all specimen testing including the identity of the personnel who performed the test.

D. Test report
      a. Reports must be sent promptly to the authorized person.
      The original report or exact duplicate of each test report including final and preliminary reports must be retained by the laboratory for a period of at least two years after the date of the reporting.
      b. Immunohematology reports must be retained by the laboratory for a period of no less than five years.
      c. For Pathology, test reports must be retained for a period of at least ten years after the date of report.
         (i) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable, and confidential manner.
            (a) For reports that are teleprinted or faxed to clients, we recommend that the client maintain confidentiality as much as possible by placing the electronic device in an area of low traffic and guarded access. Refer to UnityPoint HIPAA policies for further detail.

         (ii). Test report must indicate the name and address of the laboratory and location in which the test was performed, the test performed, the test result; and if applicable, the units of measurement.

         (iii) The Laboratory must indicate on the test report any information regarding the condition and disposition of the specimens that do not meet the laboratory's criteria for acceptability.

         (iv) Pertinent reference or normal ranges as determined by the laboratory performing the test must be available to the authorized person.

         (v) Results or transcripts of laboratory tests for examinations must be released only to authorized persons or the individual responsible for utilizing the test results.
            - Refer to the General Administration policy on Release of Information for more detail.

(vi) The Laboratory must develop and follow written procedures for reporting life threatening laboratory results or critical values.
- Refer to the policy on Critical Values for more information.

(vii) The Laboratory must, upon request, make available to clients a list of test methods used in the Laboratory and send out pertinent updates on the test information to clients whenever changes occurthat could affect the test results.

(viii) The original reports or exact duplicate must be maintained by the Laboratory in a manner that permits ready identification and timely retrieval.

E. Referral of specimens
1. Laboratory must refer specimens for testing only to a laboratory possessing a valid certification for performing that test in a specialty or subspecialty.

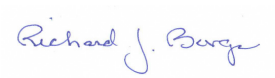
2. The referring laboratory must not revise results or information directly related to the results.
- The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who requested the test.
- The referring laboratory must maintain and be able to produce an exact duplicate of the report.
- The authorized person who orders the test or procedure must be notified by the referring laboratory the name and address of each laboratory location in which a test is performed.

V. MAINTENANCE AND STORAGE

A. All policies and procedures are reviewed every two years, (except for Safety procedures which are yearly) by Laboratory Administration and or the Medical Director of the Laboratory or designee when there are changes in practice standards, or requirements.
B. All policies and procedures are reviewed every two years (except for Safety procedures which are yearly) by staff or at the time new or revised ones are put in effect.
C. All policies are retained 8 years after being discontinued or revised.
D. All procedures are retained 2 years after being discontinued or revised

REVISION HISTORY (began using 2011)			
Rev	**Description of Change**	**Author**	**Effective Date**
2	Updated maintenance, every 2 years per CAP regulations. Added revision history chart	R. Borge	7/11/11
3	Formatting changes, system logo updated	T. Lanan	3/10/14
4	Revised to apply to both campuses, removed contracted company name for storage. Updates to reflect UnityPoint Corporation Name	R. Borge	1/27/16
5	Added clarification on unclear orders	R. Borge	9/12/16

Reviewed by

Designee	Date	Laboratory Director	Date
			1/27/16
			9/12/16