

**KAISER MEDICAL CARE PROGRAM
ORANGE COUNTY AREA
POLICIES AND PROCEDURES**

TITLE:	CLINICAL LABORATORY	INDEX NO:	05-260-01
SECTION:	PROFESSIONAL PROCEDURES	ORIGIN DATE:	9/2011
SUBJECT:	RECORD RETENTION POLICY	REVISION DATE:	8/2012, 6/2017

CLINICAL LABORATORY RECORD RETENTION POLICY

POLICY

Clinical laboratory records are retained for specific periods to meet the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and applicable state or federal laws.

RECORD RETENTION	RECORD TYPES	RETENTION PERIOD
	Manual Accession Logs	3 years
	Manual Specimen Requisitions	3 years
	Manual Patient Test Results And Reports (Downtime Records)	3 years
	Quality Control Records	3 years (5 years for transfusion medicine)
	Instrument Maintenance Records and function check records	3 years after the instrument is no longer in use.
	Proficiency Testing Records and Reports	3 years
	Quality Management Records	3 years
	Instrument Validations, Method Performance Specifications, Correlation Studies, Linearity Studies	3 Years after instrument &/or method is no longer in use
	Interfaced Instrument Printouts- Abnormal Hematology and Coagulation Results only	3 years
	Non-Interfaced Instrument Printouts	3 years
	Manual Worksheets	3 years
	Blood Bank Records (except indefinitely or permanently deferred donors and donors under surveillance)	10 years (See Blood Bank P&P)
	Indefinitely or permanently deferred blood donors and donors under surveillance	Indefinitely
	Pathology Records	See Pathology Procedure Manual and Pathology Quality Plan
	Policies and procedures	At least 3 years following discontinuance (5 years for transfusion medicine)
	Ongoing quality assessment data	3 years

<p>Individualized Quality Control Plan (IQCP), including risk assessment and supporting data, and approval of quality control plan</p>	<p>3 years following discontinuation of the IQCP</p>
<p>Personnel Records Competency assessment records</p> <p>Training records</p>	<p>3 years (5 years for transfusion medicine)</p> <p>3 years (5 years for transfusion medicine)</p>
<p>Laboratory Computer Services Computer system validation records</p> <p>Records of changes to software, the test library, and major functions of laboratory information systems</p> <p>Ongoing computer system checks (e.g. calculation verification)</p>	<p>3 years beyond the life of the system</p> <p>3 years</p>
<p>In the Event of a Facility Closure: All Records are retained for the same period of time as listed above after the date of closure.</p>	

REFERENCE CAP LABORATORY GENERAL CHECKLIST - GEN 20377

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Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ date	Lab Manager reviewed/ date	Date change Imp.
New		Mary Lou Beaumont 9/2011			
Minor	Added Retention Record: See Blood Bank P&P and Pathology Quality Plan	Lorie Padilla 8/20/2012			
Major	Added records and retention period	Judith Remolar 6/8/17	<i>Je Proc 6/8/17</i>	<i>ms Beaumont 6/8/17</i>	<i>6/8/17</i>

Imp. =Implemented

