

Laboratory Reflex Testing Policy

Purpose This document outlines the policy for reflex testing in the Southern California Laboratory Systems.

Introduction Under Medicare reimbursement rules, Medicare will cover “reflex” laboratory tests if the treating physician who orders the initial diagnostic test is aware that additional reflex tests may be performed and has been given the option of ordering the initial test without subsequent reflex tests. No additional order, whether from the attending physician, a pathologist or otherwise, is required for such reflex testing to be performed. The SCPMG Laboratory Systems criteria and exceptions for “reflex” laboratory testing follows.

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Laboratory Reflex Testing Policy, Continued

Policy

The SCPMG Laboratory Systems will automatically perform reflex tests as defined by the following list of laboratory reflex criteria (see Table A), unless the provider notifies the Laboratory Systems that the reflex is not requested. (OIG, 1998)

- An initial test has been performed as ordered;
- The initial test meets the criteria for the reflex test; and
- The SCPMG Laboratory Operations Committee has annually approved those tests and criteria as documented in the minutes of the Laboratory Operations Committee (Lab OPC); or
- A reflexive test required by accrediting agencies (e.g., CAP, TJC, COLA) or by federal or state mandates (e.g., CMS CLIA, California), or
- A reflexive test that is considered “good laboratory practice,” providing accurate clinical information to the physician.

The SCPMG Laboratory Systems’ Informatics, Systems Support & Utilization Management subcommittee (ISUM) is responsible for the implementation of this policy within the SCPMG region.

The SCPMG Laboratory Systems acknowledges that some clinical laboratory tests are mandatory to confirm an initial test result.

Definitions

Reflex Tests: Those select laboratory tests where the initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate.

Treating Physician: A physician who is treating or furnishes a consultation for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical condition. (42 C.F.R. §410.32(a)) This definition also includes nonphysical practitioners who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law (42 C.F.R. §410.32(a); MCM 15021.A.3.). (CMS, 2001)

Order: A communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). (CMS, 2001)

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Laboratory Reflex Testing Policy, Continued

Exceptions to the Reflex Policy

Reflex testing requirements do not apply to hospital inpatients, HOV or other institutional inpatients. (e.g., SNF patients) (42 C.F.R. §410.32(e))

Under MCM a pathologist may perform “additional tests, such as special stains, even though they have not been specifically requested by the treating physician/practitioner” under the following circumstances:

- The services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;
 - The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and
 - The pathologist documents in his/her report why additional testing was done. (Reese, 2005)
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Auditing and Monitoring

Compliance with this policy will be monitored and reported to the SCPMG Laboratory Operations Committee by an annual audit to include:

- Annual review by SCPMG Laboratory Operations Committee of the current reflexive testing practices as well as any new clinical laboratory industry recommendations regarding reflexive testing for appropriateness and compliance
 - Review of the LabNet Test Directory for compliance
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Non-Controlled Documents

The following non-controlled documents support this policy:

- CMS. (2001). CMS, Medicare Carriers Manual Transmittal 1725: Part III Medicare Carriers Manual
 - OIG. (1998). OIG Compliance Program Guidance for Clinical Laboratories
 - Kaiser Permanente Memorandum No. 210: Medicare Rules for “Reflex” Laboratory Testing (2005)
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Table A – Laboratory Reflex Testing Criteria (November 2013)

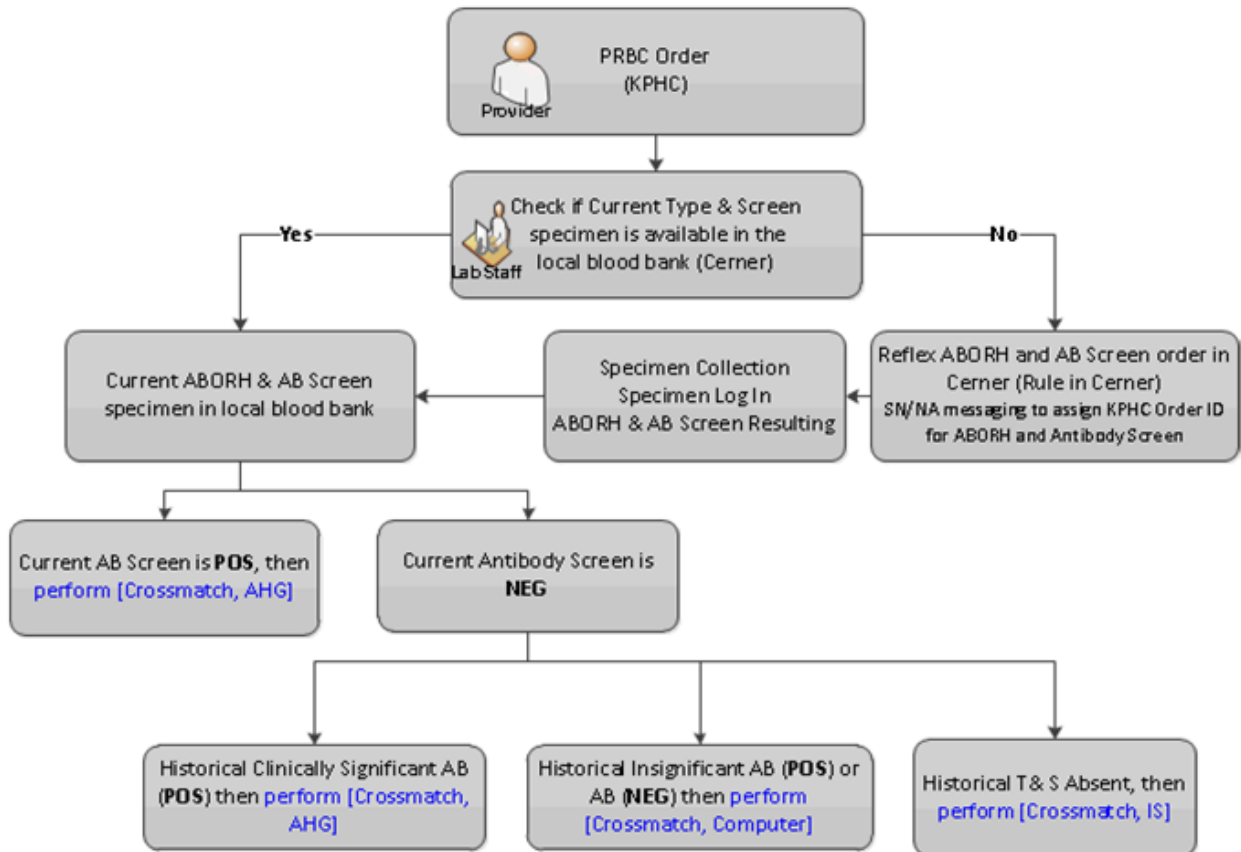
SCPMG Regional Reflex			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
CBC with Differential [85025B]	CBC with auto WBC Differential	Per regional protocol and CLS “Slide” review, as needed	Manual Differential or Cell Morphology
Fetal Lung Maturity [83664B]	Lamellar Bodies	Immature or Indeterminate Result	LS Ratio + PG
Fetal Screen [85461C]	Fetal Screen	Positive	Kleihauer Betke
Hereditary Angioedema (HAE) [85130A]	Hereditary Angioedema Panel	Indeterminate or Divergent C1 Inhibitor Function and C4	Antigenic and Functional Assay for C1 Inhibitor at the Regional Allergy Laboratory
Indirect Coombs [86885B]	Indirect Coombs	Positive	Antibody ID
Malaria Smear [850460O]	Malaria Smear	Negative or Positive	Species Confirmation and Smear Review at the Regional Reference Laboratories
PFA-100 Test for Platelet Function	PFA-100	CEPI (Collagen + Epinephrine) Positive	CADP (Collagen + ADP) Test Added
Rapid HIV Test [86703E]	Rapid HIV	Positive	HIV Confirmation at the Regional Reference Laboratories
Rapid Strep, POCT [87880C]	Rapid Strep, POCT	Negative	Throat Culture
Urinalysis w/o Microscopic [81003B]	Urinalysis, Strip	<ul style="list-style-type: none"> • RBC > = trace • Protein > = 1+ • Leukocyte esterase + • Nitrite + 	Microscopic Examination
Urine Drug Screen [219708]	Triage Urine	<ul style="list-style-type: none"> • Neonates 0-3 days • Child <14 years • Adults: Positive for PCP and Amphetamines • New Mothers: All positives 	Confirmation per Regional Protocol

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Table A – Laboratory Reflex Testing Criteria (November 2013),
 Continued

SCPMG Regional Reflex			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
Packed RBC Unit	Check for current Type and Screen in local blood bank	See Chart 1 and Table 1	Crossmatch, AHG or Crossmatch, IS or Crossmatch, Computer

Chart 1 – Reflex Algorithm for a Blood Product Order



Cross-match methods: **AHG**: Antihuman globulin, **IS**: Immediate Spin, **Computer**: Electronic

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Table A – Laboratory Reflex Testing Criteria (November 2013),
 Continued

Table 1 – Cross-match Method Based on Current and Prior Testing

Crossmatch Method		
	Current Type and Antibody (AB) Screen	
Historical Type and Antibody (AB) Screen	Current clinically significant AB or Insignificant AB (POS)	Current AB (NEG)
Not Present	Crossmatch, AHG	Crossmatch, IS
History of Clinically Significant AB (POS)		Crossmatch, AHG
History of Insignificant AB (POS) OR AB (NEG)		Crossmatch, Computer
<p>Note: Refer to the table in the Appendix to see the definition of clinically significant or insignificant antibodies. AHG: Antihuman globulin, IS: Immediate Spin, Computer: Electronic</p>		

Regional Reference Laboratories – Microbiology Services			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
AFB Smear + Culture	AFB Smear	Positive	MTD Gen-Probe TMA or MTB PCR
Antibody Screen [86885F]	Antibody Screen	Positive	Antibody ID [86850A] and Titer [86886J]
ANCA [86256Z]	ANCA	Positive	Myeloperoxidase (MPO) and Proteinase 3 (PR3)
<ul style="list-style-type: none"> • Cocci IgG and IgM, Serum [231325] • Cocci IgG and IgM, CSF [231326] 	Cocci IgG	Positive	Complement Fixation
	Cocci IgM	Positive	Immunodiffusion
Hepatitis A Virus Antibody, Total [86708C]	Hepatitis A Virus Total	Positive	Hepatitis A Virus IgM

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Table A – Laboratory Reflex Testing Criteria (November 2013),
 Continued

Regional Reference Laboratories – Microbiology Services			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
Hepatitis B Surface Antigen [87340B]	Hepatitis B Surface Antigen	Positive	Hepatitis B Surface Antigen Neutralization
Hepatitis B Core Total [86705B]	Hepatitis B Core Total	Positive	Hepatitis B Core IgM
Hepatitis C RNA Screen Qual TMA [87521H]	HCV RNA Screen Qual TMA	Positive	HCV Genotype by LiPA
HIV-1/2 EIA [86703B]	HIV-1/2 EIA	Positive	HIV-1 Western Blot
HIV -1 Western Blot	HIV- Western Blot	Indeterminate or Negative or Positive with only gp41 and p24 bands present (no 160/120 bands)	HIV-2 (reflexes to HIV-2 WB if positive)
HPV Triage (<30 years) [250323]	PAP, Cervical Bethesda Screen [88164A]	Atypical Squamous Cells of Undetermined Significance (ASCUS)	HPV, High Risk, DNA Hybrid Capture 2 [87621B]
Lyme [86618B]	Lyme	Positive	Lyme Western Blot
Syphilis Screen, Neonate (<30 Day) [86592N]	RPR	Reactive	TP-PA
Syphilis EIA [213118]	Syphilis EIA	Positive	RPR/TP-PA
Toxoplasma IgG and IgM [86777E]	IgM	Equivocal or Positive	Confirmatory Testing

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Table A – Laboratory Reflex Testing Criteria (November 2013),
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Regional Reference Laboratories – Chemistry Services			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
Alpha-1-Antitrypsin Quantitation [82103B]	Alpha-1-Antitrypsin Quantitation	< 100 mg/dL	Alpha-1 Antitrypsin Phenotyping
Alpha-1-Antitrypsin Phenotyping [82104B]	Alpha-1-Antitrypsin Phenotyping	Suspicious Phenotype	Alpha-1 Antitrypsin Quantitation
Drugs of Abuse Screen [80100A]	DAU	Positive	Confirmation per Regional Protocol
Hemoglobin Evaluation [83021B]	Hemoglobin, HPLC	Positive	Hemoglobin Electrophoresis
Lipid Panel [80061B]	Lipid Panel	Triglycerides > or = 400 mg/dL	Direct LDL
Lupus Anticoagulant Testing [85705A]	<ul style="list-style-type: none"> • aPTT (activated Partial Thromboplastin Time) (85730) • dRVVT (dilute Russell's Viper Venom Time) (85613) 	Abnormal	<ul style="list-style-type: none"> • aPTT 1:1 Mixing Study (when aPTT is abnormal) • dRVVT Confirm w/Ratio (when dRVVT is abnormal) (85613) • STA-Clot (when aPTT 1:1 mix is abnormal and dRVVT is normal or dRVVT Confirm w/Ratio is normal) (85597)
Protein Electrophoresis, Serum [84165C]	Serum Protein Electrophoresis	Monoclonal spike	Immunofixation QIG
Sickle Cell Screen [85660B]	Sickle Cell	Positive	Hemoglobin Evaluation
TSH [84443B]	TSH	Abnormal	Free T4
Urine Immunofixation Electrophoresis [86335A]	Urine Immunofixation Electrophoresis, UIFE	Evidence of Monoclonal Immunoglobulin or Bence Jones Protein	Urine Protein Electrophoresis, UPEP

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Table A – Laboratory Reflex Testing Criteria (November 2013),
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Regional Reference Laboratories – Cytopathology			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
Non-GYN Cytology – Thyroid Fine Needle Aspiration (FNA)	Non-GYN Cytology – Thyroid Fine Needle Aspiration (FNA)	2 nd AUS result (Bethesda System Category III)	Thyroid Molecular Diagnostics (Asuragen miR <i>Inform</i> ® Thyroid Panel)

Regional Anatomic Pathology			
Test Ordered [KPHC Order Code]	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
Surgical Pathology	Surgical Pathology	<ul style="list-style-type: none"> • Diagnosis of Colon Cancer • Age < 50 	Mismatch Repair Proteins (MRP) IHC MLH1, MSH2, MSH6 and PMS2 (88360)
Surgical Pathology	Surgical Pathology	Diagnosis of Breast Cancer	ER/PR IHC for in situ and/or invasive cancer (88360) HER2 IHC for invasive cancer only (88360) Note: If final diagnosis (after lumpectomy) is DCIS, then only ER and PR required
Surgical Pathology	HER2/neu IHC	Equivocal (2+) IHC	HER2/neu by FISH

Laboratory Reflex Testing Policy

HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
New - 2009					
Version 02					
Version 03	<ul style="list-style-type: none"> • Protein Electrophoresis, Urine modified per Technical Bulletin 1-19-12 • Test name corrections • Addition of KPHC test codes • Formatting changes 	MEA 2/21/12			
Version 04	<ul style="list-style-type: none"> • Removed APTT reflex to PTT Mixing Study • Added Cell Morphology to CBC w/ Differential test ordered by reflex • Added Packed RBC Unit • Added Neonates 0-3 days to reflex criteria for Urine Drug Screen • Lipid Panel reflex criteria updated to Trig \geq400 • Antibody Screen KPHC test code correction • Addition to Antibody ID and Titer KPHC test codes • Addition of RRL Cytopathology Non-Gyn Thyroid FNA • Addition of HER2/neu IHC • Test Order: Added Culture to AFB Smear • Added PAP ASCUS reflex to HPV Triage (<30 years of age only) 				

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Laboratory Reflex Testing Policy, Continued

HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
Version 04	<ul style="list-style-type: none"> • Removed specification for annual approval by Lab OPC documented in minutes. • Changed Informatics, Systems Support & Utilization Management subcommittee (ISUM) to Informatics Systems Support (ISyS) subcommittee of Lab OPC. • Deleted section on Auditing and Monitoring since there is no regulatory or accreditation requirement. 				

Laboratory Reflex Testing Policy, Continued

Reviewed and approved by (For Medical Center Area Approval Only):

SIGNATURE	DATE
Name: _____ Operations Director, Area Laboratory	
Name: _____ CLIA Laboratory Director	

Signature Manifest

Document Number: SCPMG QMS - 0049

Revision: 4

Title: Policy_Reflex Testing

All dates and times are in Pacific Standard Time.

Reflex Policy V04

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Maureen Ahler (K083442)	Quality Systems Leader	28 Feb 2014, 11:16:51 PM	Approved
Fred Ung (K057175)	SCPMG LABORATORY QCD	6 Mar 2014, 09:09:08 AM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Gary Gochman (P091953)	PATH BLOOD BANK	6 Mar 2014, 12:28:29 PM	Approved
Darryl Palmer-Toy (T188420)	RRL MEDICAL DIRECTOR	20 Mar 2014, 04:50:10 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Maureen Ahler (K083442)	Quality Systems Leader	20 Mar 2014, 07:44:08 AM	Approved