LAB Dept MEETING – Huddles

Date of Meeting: 7/31/2018
Attendees: Myrna Ocab, Jocelyn Ybarra, Priscila Dar, Tammy Rantung, Quang Trinh, Rizza Alcordo, Teresita Strickland, Mark Gomez, Elliott Faure, Melanie Magee, Janet Gerges, Juanita Fernandez, Patricia Chea, Marissa Calilung, Theda Bryant

Topic	Details	Action Item, responsible person, date due, or informational only
KUDOS SAFETY TIP	• Thank you for continuing to do the required KP Learn courses on a timely manner. • Thanks to all phlebotomists for meeting the competency deadline for 4 tubes QFT-Plus (Quantiferon)	Informational
	• Last day to take mandatory compliance training is today. July 31, 2018. • A reminder from Compliance office: Picture taking is not allowed in the workplace. We have lots of flyers/paper posted in the lab that contain private information and or PHI.	ALL STAFF
	• Annual CLS competencies due by October 8,2018- Chemistry, Urinalysis, Hematology, Microbiology. Please cooperate with the validators to get these competencies done on time. If a validator is not here and you need to be validated on a certain test system, let Marissa know so that can be done. • Troponin normal results are autoverified. The critical results need CLS intervention. If you go on break and you loaded samples on the Access 2 especially Troponin, let your co-workers know. You need to scan all samples on Cerner before storing away to make sure that everything is resulted. We don't want to miss any tests especially Troponin critical results. • CLSs need to review and initial downtime reports before faxing. These are official reports that are scanned on patients' charts. Be sure to call critical values as well. Phlebotomists should not print reports on Cerner and fax or send to ED/floors unless the CLS reviews, date and initial first. • When we have to use the DXH 800 report for downtime, use the **Chartable Report**. This has reference ranges. Do not use the **Laboratory Report**.	CLS

	• For post calibration in Chemistry, run all QCs associated with the analyte calibrated for all specimen types- serum and urine (if necessary). Do not just repeat the unacceptable QC. It is important to perform this after calibration since calibration factors changed that can affect results.	
	• We went live on 4 tubes QFT-Plus on July 25,2018. Any challenges on this?	Phlebotomist
UBT	• People Pulse is just around the corner: September 10-28,2018. How can we improve participation this year?	

This concludes the Minutes of the _7/31/2018_____ Lab Staff Meeting.

Prepared by: Marissa Calilung/Patricia Chea Date :___8/1/2018_____

Technical Bulletin

Laboratory Care Delivery System – Regional Reference Laboratories

THYROID FUNCTION TESTING IN PREGNANCY

When assessing thyroid function in pregnancy, use of trimester-specific reference ranges for TSH, free T4, and total T3 is recommended[1]. These can now be found in the table below and in LabNet. New trimester-specific test codes for TSH, free T4, and total T3 are also being built in KP HealthConnect using these ranges.

While these immunoassays are sufficient for most pregnant patients, other tests are now available for more complicated patients with thyroid dysfunction. Effective **July 18, 2018**, Total **T4 [84436B]** will be made available to order on KP HealthConnect. It may be helpful in late pregnancy, if trimester-specific reference ranges are used. **T4, FREE DIRECT DIALYSIS [84439D]** is also available, and less subject to interference from changes in the concentration of thyroid binding proteins.

1. Alexander EK et al. Thyroid 2017; 27(3):315-89.

TRIMESTER-SPECIFIC REFERENCE RANGES FOR THYROID FUNCTION TESTS

TEST	1ST TRIMESTER	2ND TRIMESTER	3RD TRIMESTER
TSH [84443B] (mcIU/mL)	0.02 – 2.69 [2]	0.15 – 3.11 [3]	0.31 – 2.90 [4]
T4 FREE [84439B] (ng/mL)	0.9 – 1.4 [2]	0.7 – 1.2 [3]	0.7 – 1.1 [4]
TRI-IODOTHYRONINE, TOTAL [84480A] (ng/dL)	104 – 247 [2]	118 – 240 [3]	91 - 206 [4]
T4 [84436B] (mcg/dL)	6.4 – 15.2 [5]	7.4 – 15.2 [5]	7.7 – 13.8 [5]
T4, FREE DIRECT DIALYSIS [84439D] (ng/dL)	0.9 - 2.0 [5]	0.8 - 1.5 [5]	0.8 - 1.7 [5]

2. La'ulu SL & Roberts WL. Clin Chem 2011; 57(6):913-5.
3. La'ulu SL & Roberts WL. Clin Chem 2007;53(9):1658-64.
4. Stricker RT, et al. Euro J of Endocrinology 2007; 157:509–514.
5. Quest Diagnostics

QUESTIONS?

Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077
Darryl E. Palmer-Toy, MD, PhD, Physician Director, SCPMG Regional Reference Core Laboratories: 818-503-7028, tie-line 397

Technical Bulletin

Laboratory Care Delivery System – Regional Reference Laboratories

TOTAL COMPLEMENT (CAE) – CHANGE IN CONTAINER REQUIREMENTS

Effective Wednesday, **July 18, 2018**, the Regional Reference Laboratories will not require a gold top tube to be drawn for **TOTAL COMPLEMENT (CAE)** testing. The only required tube for CAE testing will be the red top tube (RED7).

QUESTIONS?

Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077

Bruce J. Goldberg, MD, PhD, Physician Director of Allergy-Immunology: 818-392-7292

Technical Bulletin

Laboratory Care Delivery System – Regional Reference Laboratories

CHANGE TO QUANTIFERON-TB GOLD TESTING KITS

Effective Wednesday, **July 25, 2018**, the Laboratory Care Delivery System will switch from the QuantiFERON-TB Gold kit (3 tubes) to the QuantiFERON-TB Gold Plus kit (4 tubes), as production of the former is being discontinued by the manufacturer. Of note, blood should be drawn directly into the QFT-Plus blood collection tubes (4 tubes) and transported at room temperature to the North Hollywood Regional Reference Laboratory.

Press Ctrl + Click link to watch the QFT-Plus training videos. QFT-Plus Training Videos

QUESTIONS?

Client Service Center, 1-888-4LAB NFO, or tie line 8-397-7077
Jonathan C. Gullett, MD, Physician Director of Microbiology, jonathan.c.gullett@kp.org
Ken Van Horn, PhD, D(ABMM), Technical Director of Microbiology, ken.van-horn@kp.org

Technical Bulletin

Laboratory Care Delivery System – Regional Reference Laboratories

ACUTE MYELOID LEUKEMIA (AML) MOLECULAR GENETICS/MUTATION ANALYSIS SEND OUT PROCESS AND TEST INFORMATION

Effective immediately, the Molecular Genetic Pathology (MGP) Regional Laboratory has a new process for **ACUTE MYELOID LEUKEMIA (AML)** and **MYELOID NEOPLASMS MOLECULAR GENETICS/MUTATION ANALYSIS** send out.

The new send out test will be performed at **ARUP laboratory** (outside reference laboratory) and will entail the following assays for Blood and Bone Marrow samples with a new diagnosis or at the request of the ordering clinician for any clinical indication that the clinician determines to be relevant:

Table 1. ARUP reference test information. This table outlines two individual tests with specimen requirements.

Reference Info	ARUP Test Code	Preferred Specimen	Specimen with disclaimer	Min Volume	TAT
Myeloid Malignancies Mutation Panel by Next Generation Sequencing (NGS) – *Multiple genes, please see gene list further down in document*	ARUP - 2011117	EDTA	Sodium Heparin	1 ml	12-14 d
LeukoStrat CDx FLT3 Mutation Detection by PCR (allows for quicker TAT for FLT3 result) – *FLT3 molecular testing only – for STAT FLT3 resulting* **This test is not performed at ARUP, but is sent from ARUP to LabPMM Invivoscribe.**	ARUP -2014683	Sodium heparin	EDTA	0.5 ml	3-5 d

Table 2. Specimen requirements based on clinical test preference. Column 1 is if both Myeloid and STAT Leukostrat FLT3 are required; Column 2 is if only the Myeloid NGS panel is needed (myeloid neoplasms other than AML or AML monitoring, etc.); Column 3 is if FLT3 only is needed. The combination of tests is determined by the clinical indication from the ordering clinician.

	Column 1: Combination	Column 2: Myeloid NGS Only	Column 3: FLT3 only
Test	Myeloid Malignancies Mutation Panel (NGS) + LeukoStrat FLT3 (BM or Blood)	Myeloid Malignancies Mutation Panel (NGS) only (BM or Blood)	Leukostrat FLT3 Only
Specimen	EDTA ≥1.5 ml AND Sodium Heparin ≥1.5 ml	EDTA 1.5ml OR Sodium Heparin 1.5ml	Sodium Heparin 1.5ml

Important notes on specimen collection: **Fixed cell pellet** is **unacceptable** for any of these tests. **Bone marrow samples** should be collected in **both EDTA (LAV5, purple top)** AND **Sodium Heparin (GS4, green top)** [refer to volume requirements in above tables].

Important note on FLT3 results: When ordering both the Myeloid Malignancies NGS Panel and the Leukostrat FLT3 STAT test, a technical caveat is that there may be a difference in the result on each test for FLT3. *Example: Leukostrat FLT3 STAT test comes back with a negative result and the Myeloid Malignancies NGS Panel comes back with a positive FLT3 result.* This is most likely due to the technical differences between the methodologies used by these two tests.

Clinician instructions to Regional MGP Lab for test ordering preference (typically by hematopathologist or oncologist):

1. Clearly indicate the need for ***both or specific test preference*** for either **NGS and stat PCR for FLT3** by email (see examples for indication in placing the test order in items #2-4 below)
   Email the Laboratory mailbox: SCAL-GeneticsLaboratory-MGP-RegionalLab@kp.org
   Or the managers: Sandra.L.Gutierrez@KP.org; Angela.T.Lim@KP.org; Felicita.Wong@KP.org
2. AML New Diagnosis, AML Relapse, or related diagnosis.
   Request examples: New diagnosis AML protocol (Myeloid NGS + stat PCR for FLT3) OR AML Protocol (Myeloid NGS + Stat PCR for FLT3)
3. For other disorders/neoplasms that do not require Stat PCR for FLT3 such as MDS, MDS/MPN, MPN:
   Request example: Myeloid Malignancies Mutation Panel by NGS only
4. For remission monitoring, the preferred send out test is Myeloid Malignancies Mutation Panel (NGS) only.

Genes tested on the Myeloid Malignancies NGS panel

(*This list would be current as of the day the technical bulletin was issued, however, the list may be subject to change by the respective laboratory. The most current gene list will be on the final result report*):

ASXL1, ASXL2, BCOR, BCORL1, BRAF, BRINP3, CALR, CBL, CEBPA, CSF3R, DNMT1, DNMT3A, EED, ELANE, ETNK1, ETV6, EZH2, FLT3, GATA1, GATA2, HNRNPK, IDH1, IDH2, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, LUC7L2, MAP2K1, MPL, NOTCH1, NPM1, NRAS, NSD1, PHF6, PRPF40B, PRPF8, PTPN11, RAD21, RUNX1, SETBP1, SF1, SF3A1, SF3B1, SMC1A, SMC3, SRSF2, STAG2, SUZ12, TET2, TP53, U2AF1, U2AF2, WT1, ZRSR2

General information on results reporting:

1. These **send out tests final reports** will be scanned into the **Media Tab in KPHC**. Each test as listed in Table 1 is a separate report.
2. In general, the report displays results in two tiers:
   - **Tier 1** represents mutations/variants of **known** clinical significance in myeloid disorders.
   - **Tier 2** represents mutations/variants of **unknown** clinical significance in myeloid disorders.

   Overall, in these two categories, the report will show the mutation or variant identified in the result section. In the interpretation section, there will be an explanation of the mutation or variant with references.

   These reports may be long and have extensive information requiring careful review.

   (See next page for example ARUP NGS Myeloid Report)

Example NGS Myeloid Malignancies report from ARUP:

Result:
I. Tier 1 (Variants of known significance in myeloid malignancies):

1. CALR c.1099_1150del, p.Leu367fs (NM_004343.3)
Variant Frequency: 6.0%

Interpretation: The CALR gene encodes calreticulin which is involved in diverse cellular functions including protein folding, cell proliferation and apoptosis (Nangalia et al., 2013). Somatic mutations of CALR are typically seen in patients with myeloproliferative neoplasms (MPNs) who do not have JAK2 or MPL mutations (Klampfl et al., 2013; Nangalia et al., 2013; Tefferi and Pardanani, 2014). CALR mutations are found in 15-32% of patients with essential thrombocythemia (ET), in 16-35% of patients with primary myelofibrosis (PMF), and are uncommon in patients with polycythemia vera (PV) (Klampfl et al., 2013; Nangalia et al., 2013; Rotunno et al., 2014; Rumi et al., 2014a; Tefferi and Pardanani, 2014; Tefferi et al., 2014d). CALR mutations are mostly exon 9 deletions or insertions. This particular frameshift mutation (p.Leu367fs) has been commonly reported in MPN patients and is referred to as a type 1 CALR mutation (Klampfl et al., 2013; Nangalia et al., 2013). Type 2 CALR mutations are more frequent in ET, while type 1 are more frequent in PMF (Andrikovics et al., 2014; Cabagnols et al., 2015). In PMF, CALR mutations are associated with better overall survival (Klampfl et al., 2013; Panagiota et al., 2014; Rumi et

II. Tier 2 (Variants of unknown significance in myeloid malignancies):

1. STAG2 c.3430A>G, p.Met1144Val (NM_001042749.2)
Variant Frequency: 50.3%

Interpretation: STAG2 is a subunit of the cohesin complex which is composed of four core subunits - SMC1A, SMC3, RAD21 and STAG2. Collectively, acquired cohesin complex mutations are found in 8-13% of myelodysplastic syndrome (MDS) patients and in 12-14% of acute myeloid leukemia (AML) patients (Cancer Genome Atlas Research, 2013; Kon et al., 2013; Thota et al., 2014) but are not commonly reported in patients with a MPN. Mutations in cohesin genes are generally mutually exclusive in myeloid malignancies (Thol et al., 2014; Thota et al., 2014). In myeloid malignancies, STAG2 mutations are mostly nonsense, frameshift and splice site mutations; while STAG2 missense variants (as seen here) are less common (Thota et al., 2014). This particular STAG2 missense variant (p.Met1144Val) alters a moderately conserved amino acid and has not been reported in myeloid malignancies, to the best of our knowledge. The functional consequences are unknown. In addition, this variant is listed in dbSNP (rs147520054), and is reported in nine people in the Genome Aggregation Consortium with a minor allele frequency (MAF) of 0.00004. Given that the variant frequency is 50.3% (close to 50%) it is unclear whether this is a germline or somatic variant. The clinical significance, if any, is uncertain.

QUESTIONS?

Molecular Genetic Pathology Regional Laboratory, Client Support Services 818-502-5959, or tie line 336

Mike Moradian, PhD, Director of Operations, 818-502-5960, or tie line 336

Ruan Ramjit, MD, Physician Director, 818-502-5959, or tie line 336

Regional Reference Laboratories System Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077

Technical Bulletin

Laboratory Care Delivery System – Regional Reference Laboratories

WATER SAMPLE COLLECTION & TESTING UPDATE

Effective Wednesday, **July 25, 2018**, there will be a **change in water sample collection and testing** at the Regional Reference Laboratory.

TEST INFORMATION

SAMPLE(S) REQUIREMENT:

1. Sample port must be completely disinfected (usually with isopropyl alcohol) prior to sampling.
2. Sample collection at minimum 25mL (no more than 100mL) in a sterile container.
3. Send sample(s) with request form in a plastic bag and transport with cold packs in a cooler to SCPMG RRL-Sherman Way Solutions.

*Sample(s) Received	Sample(s) TAT Reading/Resulted Out
Wednesday	Monday
Thursday	Tuesday
Friday	Wednesday

**Sample(s) received after 12pm, may be processed the next business day*

QUESTIONS?

Your local Pathology Department

Client Service Center, 1-888-4LAB NFO, or tie line 397-7077

Solutions Preparation 818-503-6840, or tie line 397-6840

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http://kpnet.kp.org:81/california/scpmg/labnet/index.htm

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7/27/18

Technical Bulletin

Laboratory Care Delivery System – Regional Reference Laboratories

CYCLOSPORINE REBASELINING

The Laboratory Care Delivery System is pleased to announce that, effective Monday, **July 30, 2018**, the **CYCLOSPORINE** test platform will be re-baselined from an immunoassay (EIA; Beckman AU680) to liquid chromatography-tandem mass spectrometry (LCMSMS), a more highly sensitive, specific, and accurate method with lower costs. Both the EIA and LCMSMS results will be reported together during the rebaselining period (approximately 3 months), under the current existing order for EIA. Studies have shown that due to the highly specific nature of LCMSMS for the parent drug Cyclosporine A, patient values from LCMSMS will generally be lower than those by EIA. Please see second page for an example of the double result display in KPHC.

After rebaselining is completed, the order code and results will be updated for the LCMSMS method. The analyte will continue to be reported with the same units and reference ranges, and have the same specimen requirements.

TEST INFORMATION

REBASELINING INFORMATION	DETAILS
Current KPHC Order Display Name continues to be used during rebaselining period	CYCLOSPORINE LEVEL, EIA
Current KPHC Order Code	80158H
Specimen Source	Blood
CPT Code	80158
Current KRMS Procedure Code	8718671
Current LRR Result Component Name for immunoassay method result	CYCLOSPORINE, EIA
Current LRR Result CID for immunoassay method result	120969
New LRR Result Component Name for LCMSMS method result	CYCLOSPORINE
New LRR Result CID for LCMSMS method result	120967
Future KPHC Order Display Name and [code] after rebaselining period finishes	CYCLOSPORINE LEVEL [80158D]

QUESTIONS?

Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077

JiYeon Kim, MD, MPH; Physician Director, Esoteric Chemistry & Immunology, Special Coagulation: 818-503-6710 or tie line 8-397-6710

Vincent Dizon; Director of Operations, Chemistry: 818-503-7050 or tie line 8-397-7050

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REBASELINING SCREENSHOT

CYCLOSPORINE LEVEL, EIA

CYCLOSPORINE, EIA		245 ^	H
	Analytical Methodology: Enzyme Immunoassay, (EIA) by Beckman Coulter (AU-680)		
	Interpretation by physician.		
CYCLOSPORINE		230.0 ^	H

Two results for cyclosporine are provided for re-baselining purposes, as part of our transition from an immunoassay (EIA) method to a liquid chromatography-mass spectrometry (LCMS) test method. The immunoassay results are reported under the "Cyclosporine EIA" result name. The LCMS results are reported under "Cyclosporine" result name.

Narrative

RMS ACCN:
WHAT IS ORGAN TYPE:

Specimen Collected: 07/27/18 3:37 PM Last Resulted: 07/27/18 3:40 PM Lab Flowsheet Order Details View Encounter Lab and Collection Details Routing Result History