Client Update



OPKO Health Companies

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Test Name Test Code Effective Date

Carbon Dioxide, Serum (CO2) 0052 December 29, 2020

As per an in house study, the reference range for **Carbon Dioxide**, **Serum (CO2)** has been updated when performed at our Elmwood Park location. Please refer to the table below.

	Previous Test Information	New Test Information		
Reference Range	22-29 mmol/L	19-29 mmol/L		

dRVVT Complete Panel 5730 February 7, 2021

Due to the change in reagents and methodology at our reference laboratory, the reference ranges for the **dRVVT Complete Panel** have been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	dRVVT Test: 31.7-46.2 secs	dRVVT Test: 30.9-45.5 secs
	dRVVT Confirm: 32.9-39.6 secs	dRVVT Confirm: 30.4-43.1 secs
	dRVVT Ratio: < 1.27 ratio	dRVVT Ratio: < 1.26 ratio
	dRVVT Mix: 33.6-42.4 secs	dRVVT Mix: 33.4-41.9 secs

HPV PRIMARY 25 YRS AND OLDER RFX TO PAP

H852

January 21, 2021

HPV PRIMARY 25 YRS AND OLDER RFX TO PAP will now reflex to Pap for all HPV positive samples: Types non-16/18, 16, 18. Previously this code only reflexed to a Pap for Type non 16/18 positivity.

This change is in line with the new ASCCP Guideline: "When primary HPV screening is used, performance of an additional reflex triage test (e.g., reflex cytology) for all positive HPV tests regardless of genotype is preferred (this includes tests positive for genotypes HPV 16/18).

	Previous Test Information	New Test Information		
Profile Components	HPV DNA 16, 18, non 16/18 rfx to PAP when non	HPV DNA 16, 18, non 16/18 rfx to cytology when		
	16/18 positive	positive		

MTHFR C677T 5764 March 1, 2021 MTHFR A1298C 5765

In reports¹ the clinical significance of the MTHFR C677T (test code 5764) and MTHFR A1298C (test code 5765) mutations in relation to thrombosis has been questioned. The data indicate that the MTHFR mutations do not correlate well with thrombosis. Therefore, the Special Coagulation laboratory will no longer offer these two tests. To monitor the hyperhomocysteinemia, one could measure the serum homocysteine (test code 5755) level directly.

1. No Association Between the Common MTHFR 677C \rightarrow T Polymorphism and Venous Thrombosis: Results From the MEGA Study. Irene D. Bezemer, MSc; Carine J. M. Doggen, PhD; Hans L. Vos, PhD; et al. https://iamanetwork.com/journals/jamainternalmedicine/fullarticle/769649

Total Protein S Antigen 5789 March 1, 2021

Due to the change in reagents and methodology at our reference laboratory, the reference ranges for **Total Protein S Antigen** have been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	Male: 75-140%	Male: 81-153%
	Female: 60-140%	Female: 70-158%

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Test Name Test Code Effective Date

OnkoSight Advanced Solid Tumor NGS Panel

HSV1 HSV2, LGV

116 February 1, 2021

The Cancer Genomics Department is constantly evaluating the gene content of our solid tumor panels. Effective February 1st, GenPath will remove ALK and SRC genes from TJ16 (OnkoSight Advanced Solid Tumor). They will be replaced with BRCA1 and BRCA2. ALK and SRC point mutation/indels would be of limited diagnostic, prognostic, or therapeutic significance. The laboratory has had requests for miscellaneous solid tumors (e.g., a recent case of carcinoma ex-pleomorphic adenoma), as well as poorly differentiated carcinomas of uncertain origin or histogenesis. In these instances BRCA1/2 mutations may be potentially clinically actionable, if identified. This update does not change to the overall number of genes, CPT coding or any established pricing. Of note, the ALK gene will remain a part of the Lung Cancer Panel (TH49-0), and the SRC gene remains a part of the Melanoma Panel (TH59-9).

	Previous Test Information	New Test Information
Profile Components	AKT1, ALK, APC, ARID1A, ATM, BRAF, CDH1,	AKT1, APC, ARID1A, ATM, BRAF, BRCA1, BRCA2, CDH1,
	CDKN2A, CTNNB1, EGFR, EPCAM, ERBB2, ERBB4,	CDKN2A, CTNNB1, EGFR, EPCAM, ERBB2, ERBB4,
	FBXW7, FGFR1, FGFR2, FGFR3, GNA11, GNAQ,	FBXW7, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, GNAS,
	GNAS, HRAS, IDH1, IDH2, KDR, KIT, KRAS, MEN1,	HRAS, IDH1, IDH2, KDR, KIT, KRAS, MEN1, MET, MLH1,
	MET, MLH1, MSH2, MSH6, NOTCH1, NRAS,	MSH2, MSH6, NOTCH1, NRAS, PDGFRA, PIK3CA, PMS2,
	PDGFRA, PIK3CA, PMS2, POLE, PTEN, PTPN11, RB1,	POLE, PTEN, PTPN11, RB1, RET, SMAD4, SMO, STK11,
	RET, SMAD4, SMO, SRC, STK11, TERT, TSC1, TSC2,	TERT, TSC1, TSC2, TP53, VHL
	TP53, VHL	

--- REGIONAL REMINDER: FOR NON-NY CLIENTS ONLY---

HSV 1 HSV 2 reflex to VZV K766 January 4, 2021 HSV 1 HSV 2 J156 / L010 HSV 1 B897 / J847/6351 HSV₂ B898 /J848/ 6352 HSV 1 HSV 2 J521 T. Pallidum 6354 6356 HSV1 HSV2, T. Pallidum Q301

Please be reminded that largely due to ongoing issues related to vendor specific reagent and instrumentation shortages required to perform Genital Ulcer test, largely related to HSV, HSV reflexing to VZV, and other testing, the laboratory is temporarily suspending the use of affected platforms for HSV testing under the following test codes and recommend the corresponding alternate test codes:

P764

Suspended Test Information			Alternate Test Information				
Test Name	Test	Specimen Collection	TAT	Test Name	Test Code	Specimen Collection	TAT
	Code						
HSV 1/2 Reflex to VZV	K766	TP / SP	5-7	HSV 1/2 Reflex to	L009	SV, M4 Media***	5-7
				VZV			
HSV 1/2	J156*	TP / SP	5-7	HSV 1/2	H760**	SV, M4 Media***	5-7
	L010	Aptima Swab			or		
					Q187**	BD UVT-UTM^	
HSV1	B897	TP / SP	5-7	HSV1	J164	SV, M4 Media***	5-7
	6351	TP/SP			B238	BD UVT-UTM^	
	J847	Aptima Swab					

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Test Name			Test Code Effective Date		ive Date			
HSV2	B898 6352 J848	TP / SP TP/SP Aptima Swab	5-7	HSV2	J165 B239	SV, M4 Media*** BD UVT-UTM^	5-7	
HSV 1/2	J521	Lavender top EDTA	5-7	No alternative test available at this time				
T. Pallidum LGV HSV 1/2, T.Pallidum HSV 1/2, LGV	6354 6356 Q301 P764	TP / SP	5-7	Alternate test codes to be available soon. Temporarily not-orderable.				

^{*}J156 test components: B897, B898

Code Q265, replace Herpes with H760 or Q187

-END-

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^{**}H760 test components: J164, J165; Q187 test components: B238, B239

^{***}Swab Viral Culturette or M4 Media Supply number: 509

[^]BD UVD-UTM Supply number: 34268