

Date: July 22, 2005
Subject: Nichols' Diagnostic Kits and Test Availability

Nichols Institute Diagnostics has placed a temporary hold on a number of their diagnostic products as part of a new quality initiative. Their bulletin (Customer Bulletin No. CB-05-20) indicates that there will be delays in supplying clients with reagent kits. The bulletin also says: "We cannot speculate at this time how long the review process may take or when any particular product will become available."

Specialty is able to meet client needs for the tests that Nichols has taken down. For the majority of these assays we have already been running tests with reagents provided by vendors other than Nichols. In a few cases, we have an ample supply of Nichols kits obtained prior to the quality initiative production halt. These products are in no way problematic and none have presented with quality issues. We are evaluating and in some cases changing to alternate vendors to avoid a test delay once we run out of the Nichols kits. We are currently validating the alternate kits and anticipate having them completed shortly. Finally, Nichols has initiated production again on a few products that are now generally available.

We are continuing to run the following kits from other vendors (non-Nichols kits) for:

Test Name	Specialty Test Code	Specimen Requirement	Method	Reference Range
Adrenocorticotrophic Hormone	#3102	1(0.5) mL EDTA Plasma; frozen	ICMA	6-46 pg/mL
Aldosterone	#3104	2 (0.8) mL Serum; refrigerated or frozen	RIA	<32 ng/dL
Alpha Fetoprotein Maternal Serum 2.0 and 2.5 MOM	#3108 and #3090	3 (1.5) mL Serum; Ambient, refrigerated or frozen	CL	By report
Alpha Fetoprotein Tumor Marker	#3109	2 (0.7) mL Serum; refrigerated or frozen	CL	<6 ng/mL
Calcitonin	#3126	2 (0.8) mL Serum; frozen	CL	<13 pg/mL
Cortisol	#3128	3 (0.8) mL Serum; refrigerated or frozen. Two samples collected am/pm	By ICMA AGE	Units= ug/dL REFERENCE RANGE AM PM 0 - 23 Months 1.0 - 34.0 1.0 - 30.0 2 - 10 Years 1.0 - 33.0 1.0 - 24.0 11- 18 Years 1.0 - 28.0 1.0 - 22.0 > 18 Years 4.3 - 22.4 3.0 - 16.7
Cortisol, Free 24hr Urine UltraQuant®	#3129U	10 (5) mL 24hr Urine; ambient, refrigerated or frozen	LC/MS-MS	<45 ug/24hr
C-peptide	#3140	3 (0.8) mL Serum; refrigerated or frozen	ICMA	0.80-3.90 ng/mL
Dehydroepiandrosterone-Sulfate (DHEA-S)	#3150	2 (0.4) mL Serum; ambient, refrigerated or frozen	ICMA	Males 80-560 ug/dL Females 35-430 ug/dL

Test Name	Specialty Test Code	Specimen Requirement	Method	Reference Range
Erythropoietin	#1160	1 (0.5) Serum; ambient, refrigerated or frozen	CL	3.7-31.5 mU/mL
Estriol, Unconjugated	#3156	1 (0.2) Serum; ambient, refrigerated or frozen	CL	>18 Male: < 0.25 ng/mL Female: < 0.30 ng/mL Female (pregnant): 18 2.4 - 7.2 30 4.1 - 17.9 19 2.7 - 8.0 31 4.6 - 19.9 20 3.0 - 9.0 32 5.1 - 22.1 21 3.3 - 10.1 33 5.7 - 24.4 22 3.8 - 11.2 34 6.3 - 27.0 23 4.2 - 12.5 35 7.0 - 29.7 24 4.4 - 13.2 36 7.7 - 30.0 25 4.4 - 13.3 37 > 8.5 26 4.4 - 13.4 38 > 9.3 27 2.9 - 12.7 39 > 10.2 28 3.3 - 14.3 40 > 11.1 29 3.7 - 16.0
Ferritin	#3170	2 (1.0) Serum; refrigerated or frozen	ICMA	Male 18 - 323 ng/mL Female Premenopausal 10 - 282 ng/mL Postmenopausal 14 - 233 ng/mL
Growth Hormone	#3182	1 (0.5) Serum; ambient, refrigerated or frozen; fasting 12 hours	ICMA	<10 ng/mL
<i>Helicobacter pylori</i> IgA Abs	#7986	1 (0.4) Serum; ambient, refrigerated or frozen	EIA	< 0.89 Index
<i>Helicobacter pylori</i> IgG Abs	#7761	1 (0.4) Serum; ambient, refrigerated or frozen	EIA	< 0.89 Index
Human Chorionic Gonatropin, Beta	#3184	1 (0.5) Serum; ambient, refrigerated or frozen	CL	<5.0 mIU/mL
Insulin-Like Growth Factor I	#3220	1 (0.5) Serum; refrigerated or frozen	CL	Age Males Females (ng/mL) ----- 0 - 5 Y 17-248 17-248 6 - 8 Y 88-474 88-474 9 - 11 Y 110-565 117-771 12 - 15 Y 202-957 261-1096 16 - 24 Y 182-780 182-780 25 - 39 Y 114-492 114-492 40 - 54 Y 90-360 90-360 >54 Y 71-290 71-290
Insulin	#3192	1 (0.5) Serum; refrigerated or frozen	CEIA	3.0-28.0 mU/L
PTH, Intact Only	#3941	1 (04) Serum; frozen	CEIA	11.1-79.5 pg/mL
Thyroglobulin Serum	#3255	2 (0.5) Serum; ambient, refrigerated or frozen	ICMA	<60 ng/mL
Thyroglobulin Autoantibodies	#1110	1 (0.4) Serum; ambient, refrigerated or frozen	ICMA	<60 U/mL
Thyroid Peroxidase Autoantibodies	#3062	1 (0.2) Serum; ambient, refrigerated or frozen	ICMA	<60 U/mL

Test Name	Specialty Test Code	Specimen Requirement	Method	Reference Range
Thyroid Stimulating Hormone, Third Generation	#3250	2 (0.8) Serum; refrigerated or frozen	ICMA Age Males Females (uIU/mL) ----- 0 - 3 D 1.00-20.00 1.00-20.00 4 D - 1 M .50- 6.50 .50-6.50 2 M - 5 M .50- 6.00 .50-6.00 6 M - 18 Y .50-4.50 .50-4.50 > 18 Y .35-5.50 .35-5.50	
Triiodothyronine (T3), Free	#3234	2 (1.0) Serum; refrigerated or frozen	ICMA	2.3 – 4.2 pg/mL
Vitamin D, 1,25-Dihydroxy (Calcifidol)	#3520	4 (2.0) Serum; ambient, refrigerated or frozen	RIA	25.1 – 66.1 pg/mL
Vitamin D, 25-Hydroxy (Calciferol)	#3521	1 (0.4) Serum; refrigerated or frozen	CL	10.0-60.0 ng/mL

These tests currently using Nichols kits are under evaluation:

Test Name	Specialty Test Code	Current Status
Antidiuretic Hormone	#3116	Product again available from Nichols
Bio-Intact PTH	#3949	Product again available from Nichols
Insulin-Like Growth Factor Binding Protein (IGFBP-3)	#3959	Test currently available; alternate kit under evaluation
Osteocalcin	#3550	Product again available from Nichols
PTH-Related Protein	#3990	Test currently down; alternate kit under evaluation
Renin, Direct	#3217	Test currently available; alternate kit under evaluation
Thyroxine, Direct Dialysis	#3954	Product again available from Nichols
Transferrin Receptor, Soluble	#1520	Test currently down; alternate kit under evaluation

If you have any questions or would like additional information on these tests, please contact your local *Specialty* Representative, visit our Web site at www.specialtylabs.com or call Client Services at 800-421-4449.