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NEW TESTS IN JULY

July 7, 2011

Dear Colleague:

Pathology, Inc. is pleased to announce the addition of seven new tests to our Women's Health Menu:

[5402] HPV 16/18 Genotyping (Cervista): This FDA cleared* molecular assay identifies and differentiates the two most common high-risk types of HPV linked to cervical cancer. *FDA clearance on ThinPrep® specimens; Pathology, Inc. has internally validated this assay on SurePath™ specimens.

[4266] VZV IgG: Serological determination of past, recent, or current infection. Assessment of immune status to VZV in pregnant women and neonates. Used to screen patients for exposure to Varicella zoster virus.

[4264] Measles IgG: Serological determination of immune status following vaccination or seroconversion following infection. Assessment of measles serological status in pregnant women is linked to premature delivery or spontaneous abortion. Used to screen patients for exposure/immunity to measles.

[4265] Mumps IgG: Aid in the diagnosis of mumps infection. Serological determination of immune status to mumps virus (vaccination). Used to screen patients for exposure/immunity to the mumps virus.

[4261, 4262, 4263] Cardiolipin IgG, IgM, IgA: As an aid in the diagnosis of blood clotting disorders often associated with recurrent miscarriage and other pregnancy complications, and as an aid in the diagnosis of autoimmune disorders such as SLE and others.

We thank you for choosing Pathology, Inc. and look forward to your continued support. For additional information, please visit our website at www.pathologyinc.com or contact client services at 877-922-7284.

Sincerely,

Alfred Lui, M.D.
Chief Medical Officer

New Tests (Pathology, Inc.)

5402 HPV Genotyping 16,18 (Cervista)

(Available July 7, 2011)

Component	Method	Reference Range/Units
HPV type 16	Invader by Cervista	Not Detected
HPV type 18	Invader by Cervista	Not Detected

Specimen/Stability	ThinPrep® or SurePath™ Liquid-based Pap: Stable 30 days ambient temperature
Collection Instructions	Specimens collected with a broom-type collection device and placed in Cytoc PreservCyt Solution or SurePath™ Preservation Fluid
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	Individually identifies and differentiates high-risk HPV types 16 and 18.

4266 Varicella Zoster Virus (VZV) IgG Antibodies

(Available July 7, 2011)

Component	Method	Reference Range/Units
VZV IgG Antibodies	ELISA	<0.9 Index values; Negative, presumed non-immune to VZV infection; ≥0.9-1.1 Index values; Equivocal, recommend retesting in 2 weeks if indicated; ≥1.1 Index values; Positive, presumed immune to VZV infection

Specimen/Stability	1.0 mL (minimum 0.5 mL) Serum. Transport tubes at ambient temperature or refrigerated. Samples should be stored refrigerated if not tested immediately. Freeze samples at or below -20°C if the sample is not assayed within 48 hours. Stable 7 days refrigerated.
Collection Instructions	SST or Red Top tube
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	Serological determination of past, recent, or current infection. Assessment of immune status to VZV in pregnant women and neonates. Aid in the diagnosis of disease caused by Varicella-zoster virus. Used to screen patients for exposure to chickenpox or shingles.

4265 Mumps IgG Antibodies

(Available July 7, 2011)

Component	Method	Reference Range/Units
Mumps IgG Antibodies	ELISA	<0.9 Index Value; Negative, presumed non-immune to mumps infection; ≥0.9-<1.1 Index Value; Equivocal, recommend retesting in 2 weeks if indicated; ≥1.1 Index Value; Positive, presumed immune to mumps infection.

Specimen/Stability	1.0 mL (minimum 0.5 mL) serum. Transport tubes at ambient temperature or refrigerated. Samples should be refrigerated if not tested immediately. Freeze samples at or below -20°C if the sample is not assayed within 24 hours.
Collection Instructions	SST or Red Top tube
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	Aid in the diagnosis of mumps infection. Serological determination immune status to mumps virus (vaccination). Used to screen patients for exposure/immunity to the mumps virus.

4264 Measles (Rubeola) IgG Antibodies)**(Available July 7, 2011)**

Component	Method	Reference Range/Units
Measles IgG Antibodies	ELISA	<0.9 Index Value--Negative, presumed non-immune to measles infection; ≥0.9-<1.1 Index Value--Equivocal, recommend retesting in 2 weeks if indicated; ≥1.1 Index Value--Positive, presumed immune to measles infection

Specimen/Stability	1.0 mL (minimum 0.5 mL) of serum. Transport tubes at ambient temperature or refrigerated. Samples should be refrigerated if not tested immediately. Freeze samples at or below -20°C if the sample is not assayed within 48 hours.
Collection Instructions	SST or Red Top tube
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	Serological determination of immune status following vaccination or seroconversion following infection. Assessment of measles serological status in pregnant women is linked to premature delivery or spontaneous abortion. Used to screen patients for exposure/immunity to measles.

4261 Cardiolipin IgG Antibodies**(Available July 7, 2011)**

Component	Method	Reference Range/Units
Cardiolipin IgG Antibodies	ELISA	< 23 GPL

Specimen/Stability	1.0 mL (minimum 0.5 mL) of serum or plasma. Transport tubes at ambient temperature or refrigerated. Samples should be refrigerated if not tested immediately. Freeze samples at or below -20°C if the sample is not assayed within 72 hours.
Collection	SST or Red Top tube
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	As an aid in diagnosis of blood clotting disorders. As an aid in diagnosis of autoimmune disorders, such as SLE and others. As an aid in diagnosis of cardiovascular disorders related to thrombosis. Determine the cause of recurrent miscarriage and other pregnancy complications. Used to screen patients with autoimmune disorders.

4262 Cardiolipin IgM Antibodies**(Available July 7, 2011)**

Component	Method	Reference Range/Units
Cardiolipin IgM Antibodies	ELISA	< 11 MPL

Specimen/Stability	1.0 mL (minimum 0.5 mL) of serum or plasma. Transport tubes at ambient temperature or refrigerated. Samples should be refrigerated if not tested immediately. Freeze samples at or below -20°C if the sample is not assayed within 72 hours.
Collection	SST or Red Top tube
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	As an aid in diagnosis of blood clotting disorders. As an aid in diagnosis of autoimmune disorders such as SLE and others. As an aid in diagnosis of cardiovascular disorders related to thrombosis. Determine the cause of recurrent miscarriage and other pregnancy complications. Used to screen patients with autoimmune disorders.

4263 Cardiolipin IgA Antibodies**(Available July 7, 2011)**

Component	Method	Reference Range/Units
Cardiolipin IgA Antibodies	ELISA	< 22 APL

Specimen/Stability	1.0 mL (minimum 0.5 mL) of serum or plasma. Transport tubes at ambient temperature or refrigerated. Samples should be refrigerated if not tested immediately. Freeze samples at or below -20°C if the sample is not assayed within 72 hours.
Collection	SST or Red Top tube
Schedule	Tues, Thurs
Report	3 days
Clinical Utility	As an aid in diagnosis of blood clotting disorders. As an aid in diagnosis of autoimmune disorders such as SLE and others. As an aid in diagnosis of cardiovascular disorders related to thrombosis. Determine the cause of recurrent miscarriage and other pregnancy complications. Used to screen patients with autoimmune disorders.