

October, 2004

Dear Colleague:

Last month, in anticipation of cold and flu season, we introduced the Respiratory Virus DetectR™ (Hexaplex®) with Influenza A & B RNA, Parainfluenza 1,2,3 RNA and Respiratory Syncytial Virus RNA by PCR. This month we are pleased to offer the Respiratory Virus DetectR™ PLUS (Hexaplex® PLUS) that also includes Metapneumovirus RNA by PCR. We are also introducing an EIA test for free metanephrines and normetanephrines used to assess patients for pheochromocytoma.

*Specialty* is reintroducing Interleukin 12 testing for use in monitoring the initiation of cell-mediated responses to microbial pathogens, viral infections and metastatic cancers. A number of individual autoimmune neurology assays were brought back earlier this month; for information on these assays, please visit our Website ([www.specialtylabs.com](http://www.specialtylabs.com)) or contact Client Services at 800-421-4449.

Please note that our serum opiates EIA screen assay is not appropriate for therapeutic drug monitoring of Oxycodone.

Recent communiqués from both BD Diagnostics and Bayer Healthcare Diagnostics Division have implicated the BD gel separator SST tubes as a source of bias in certain assays. Bias may vary depending on SST lot and analytical platform used. The effect, if any, of using SST tubes produced by other manufacturers has not yet been verified; however, following good laboratory practice, we will observe BD recommendations concerning the use of these tubes in the assays listed in their communiqué. This means we will begin rejecting samples that arrive in gel separator SST tubes for these tests. *Specialty* has previously discouraged the use of SST tubes for shipping. Because most of the tests that *Specialty* receives are already aliquotted into pour-off tubes, *Specialty* has no way to verify which tubes clients are using for their original sample draws; however, we strongly urge you to read the enclosed communications in detail to see which tests may be affected and we encourage you to follow these recommendations until further notice. If you have immediate questions, please contact Client Services at 800-421-4449.

In addition to previously mentioned thyroid testing, specimens collected in SST tubes are NOT acceptable for the following tests:

|      |   |        |   |
|------|---|--------|---|
| 3226 | Thyroxine (T4)                          | 3134   | CA 27.29  |
| 3230 | Thyroxine, Free Index                   | 3134SR | CA 27.29 with serial reporting                                |
| 3954 | Thyroxine Free, Direct Dialysis         | 2020   | Follicle-Stimulating Hormone & Luteinizing Hormone Evaluation |
| 3522 | Folate                                  |        |   |
| 3020 | Vitamin B12 & Folate                    | 2016   | Infertility: Endocrine Evaluation (Female)                    |
| 3504 | Vitamin B12 (Cyanocobalamin)            | 2017   | Infertility: Endocrine Evaluation (Male)                      |
| 3507 | Vitamin B12 EvaluatR™                   | 2023   | Polycystic Ovary Evaluation                                   |
| 3605 | Pernicious Anemia EvaluatR™ with reflex | 3174   | Follicle-Stimulating Hormone                                  |

For additional information, please contact Client Services at 800-421-4449.



Michael C. Dugan, M.D.  
Vice President and Co-Director of Laboratory



## New from *Specialty*

Effective Tuesday, October 26, 2004 or as noted

### 3812 Interleukin 12 Serum

| Component               | Method   | Reference Range | Units |
|-------------------------|--|-----------------|-------|
| Interleukin 12 serum    | EIA  | < 35 pg/mL      |       |
| <b>Specimen</b>         | 2 (1) mL Serum, Strict frozen  |                 |       |
| <b>Stability</b>        | Frozen – 2 Month(s)  |                 |       |
| <b>Collection Notes</b> | Split into 2 plastic vials and freeze within 1 hour of collection. Ship frozen on dry ice by <i>Specialty</i> or overnight courier. Please note any delay in freezing sample on the requisition/order. |                 |       |
| <b>Clinical Utility</b> | IL-12 serves as the initiator of cell-mediated immunity and may have therapeutic utility in mediating responses to microbial pathogens, viral infections and metastatic cancers.                       |                 |       |
| <b>Schedule</b>         | Wed  |                 |       |
| <b>Turnaround Time</b>  | 1 – 8 days   |                 |       |
| <b>CPT Code</b>         | 83520  |                 |       |

### 3812PL Interleukin 12 Plasma

| Component               | Method   | Reference Range | Units |
|-------------------------|--|-----------------|-------|
| Interleukin 12 plasma   | EIA  | 15-150 pg/mL    |       |
| <b>Specimen</b>         | 2(1) mL EDTA Plasma, Strict frozen   |                 |       |
| <b>Stability</b>        | Frozen – 2 Month(s)  |                 |       |
| <b>Collection Notes</b> | Split into 2 plastic vials and freeze within 1 hour of collection. Ship frozen on dry ice by <i>Specialty</i> or overnight courier. Please note any delay in freezing sample on the requisition/order. |                 |       |
| <b>Clinical Utility</b> | IL-12 serves as the initiator of cell-mediated immunity and may have therapeutic utility in mediating responses to microbial pathogens, viral infections and metastatic cancers.                       |                 |       |
| <b>Schedule</b>         | Wed  |                 |       |
| <b>Turnaround Time</b>  | 1 – 8 days   |                 |       |
| <b>CPT Code</b>         | 83520  |                 |       |

### 3812F Interleukin 12 Fluid

| Component               | Method   | Reference Range | Units |
|-------------------------|--|-----------------|-------|
| Interleukin 12 fluid    | EIA  | by report       |       |
| <b>Specimen</b>         | 2(1) mL Fluid, Strict frozen   |                 |       |
| <b>Stability</b>        | Frozen – 2 Month(s)  |                 |       |
| <b>Collection Notes</b> | Split into 2 plastic vials and freeze within 1 hour of collection. Ship frozen on dry ice by <i>Specialty</i> or overnight courier. Please note any delay in freezing sample on the requisition/order. |                 |       |
| <b>Clinical Utility</b> | IL-12 serves as the initiator of cell-mediated immunity and may have therapeutic utility in mediating responses to microbial pathogens, viral infections and metastatic cancers.                       |                 |       |
| <b>Schedule</b>         | Wed  |                 |       |
| <b>Turnaround Time</b>  | 1 – 8 days   |                 |       |
| <b>CPT Code</b>         | 83520  |                 |       |

### 3317 Metanephrines, Plasma Free

| <b>Component</b>             | <b>Method</b>   | <b>Reference Range</b> | <b>Units</b> |
|------------------------------|---|------------------------|--------------|
| Metanephrine, Plasma Free    | EIA   | < 0.46                 | nmol/L       |
| Normetanephrine, Plasma Free | EIA   | < 1.09                 | nmol/L       |
| <b>Specimen/Stability</b>    | 5 (2.5) mL Plasma EDTA; Lavender<br>Refrigerated – 3 Day(s), Frozen – 2 Month(s)  |                        |              |
| <b>Collection Notes</b>      | Avoid hemolysis. Do not send icteric or lipemic specimens.  |                        |              |
| <b>Clinical Utilities</b>    | Increased levels of normetanephrine and metanephrine can be found in patients suffering from pheochromocytoma, ganglioneuroma and neurogenic factors. |                        |              |
| <b>Schedule</b>              | Tuesday, Thursday, Saturday   |                        |              |
| <b>Turnaround Time</b>       | 3-5 days  |                        |              |
| <b>CPT Code</b>              | 83835   |                        |              |
| <b>Notes</b>                 | Physical and emotional stress usually cause an increase in metanephrine levels.   |                        |              |

### 1828 Metapneumovirus, Human (hMPV) RNA DetectR™

| <b>Component</b>                 | <b>Method</b>  | <b>Reference Range</b> | <b>Units</b> |
|----------------------------------|--|------------------------|--------------|
| Human Metapneumovirus (hMPV) RNA | RT-PCR   | Not detected           |              |
| <b>Specimen/Stability</b>        | Nasopharyngeal or Throat Swab; Viral Transport Media<br>Refrigerated – 4 Day(s), Frozen – 2 Month(s)   |                        |              |
| <b>Alternate Specimens</b>       | 1 (0.5) mL Nasopharyngeal Wash; 1 (0.5) mL Bronchoalveolar Lavage (BAL);<br>1 (0.5) mL Sputum; Sterile Tube  |                        |              |
| <b>Collection Notes</b>          | Collect nasopharyngeal or throat swab specimen and immediately insert into viral transport media. Collect nasopharyngeal wash, BAL and sputum specimens in a sterile container. Refrigerate prior to shipping. If shipping delayed, freeze specimen. Do not allow specimen to dry out or thaw (once frozen). Ship by overnight courier with 24 hours.                      |                        |              |
| <b>Clinical Utility</b>          | Detects human Metapneumovirus (hMPV) RNA in clinical respiratory samples. HMPV cannot be detected using classical virus culture. Recently discovered, the virus is often present in late winter and early spring respiratory infections in pediatric patients, who are otherwise virus culture and/or DFA negative for the more commonly associated respiratory pathogens. |                        |              |
| <b>Schedule</b>                  | Wednesday, Friday, Sunday  |                        |              |
| <b>Turnaround Time</b>           | 2-4 days   |                        |              |
| <b>CPT Code</b>                  | 87798  |                        |              |
| <b>Notes</b>                     | Repeated freeze thaws of specimen must be avoided, since reduced sensitivity may result due to viral RNA degradation   |                        |              |

### 7523 Respiratory Virus DetectR™ Plus (Hexaplex® Plus)

| <b>Component</b>                | <b>Method</b>  | <b>Reference Range</b> | <b>Units</b> |
|---------------------------------|--|------------------------|--------------|
| Influenza A Virus RNA           | RT-PCR   | Not detected           |              |
| Influenza B Virus RNA           | RT-PCR   | Not detected           |              |
| Parainfluenza 1 Virus RNA       | RT-PCR   | Not detected           |              |
| Parainfluenza 2 Virus RNA       | RT-PCR   | Not detected           |              |
| Parainfluenza 3 Virus RNA       | RT-PCR   | Not detected           |              |
| Respiratory Syncytial Virus RNA | RT-PCR   | Not detected           |              |
| hMPV, Human Metapneumovirus RNA | RT-PCR   | Not detected           |              |
| <b>Specimen/Stability</b>       | Nasopharyngeal or Throat Swab; Viral Transport Media<br>Refrigerated – 4 Day(s), Frozen – 2 Month(s)   |                        |              |
| <b>Alternate Specimens</b>      | 1 (0.5) mL Nasopharyngeal Wash; 1 (0.5) mL Bronchoalveolar Lavage (BAL);<br>1 (0.5) mL Sputum; Sterile Tube  |                        |              |
| <b>Collection Notes</b>         | Collect nasopharyngeal or throat swab specimen and immediately insert into viral transport media. Collect nasopharyngeal wash, BAL and sputum specimens in a sterile container. Refrigerate prior to shipping. If shipping delayed, freeze specimen. Do not allow specimen to dry out or thaw (once frozen). Ship by overnight courier with 24 hours.  |                        |              |
| <b>Clinical Utilities</b>       | Detects Influenza Virus A and B, Parainfluenza Virus 1, 2 & 3, Respiratory Syncytial Virus, and human Metapneumovirus (hMPV) RNA in clinical respiratory samples. Assay is a rapid alternative to classical virus culture with enhanced sensitivity for Influenza, Parainfluenza, and RSV. Metapneumovirus is often found in late winter and early spring in pediatric patients expressing respiratory infection symptomatology, yet culture and/or DFA negative for the other more commonly associated respiratory pathogens. |                        |              |
| <b>Schedule</b>                 | Wednesday, Friday, Sunday  |                        |              |
| <b>Turnaround Time</b>          | 2-4 days   |                        |              |
| <b>CPT Code</b>                 | 87798x6  |                        |              |
| <b>Notes</b>                    | Repeated freeze thaws of specimen must be avoided, since reduced sensitivity may result due to viral RNA degradation   |                        |              |

# Test Changes

**Effective Tuesday, October 26, 2004 or as noted**

| <u>Test Code</u> | <u>Test Name</u>   | <u>Specific Change</u>   | <u>Also Affected</u>   |
|------------------|--|--|--|
| M6               | Allergen – <i>Alternaria tenuis</i> (Alternata) IgG (formerly <i>A. tenuis</i> ) | <u>Name</u><br>Allergen – <i>Alternaria alternata</i> IgE  | All custom, regional, childhood panels that contain M6.  |
| G71              | Allergen – Canary grass reed IgE   | <u>Name</u><br>Allergen – Canary grass IgE   | All custom, regional, childhood panels that contain G71.   |
| 3092             | Alpha-Fetoprotein Quad Screen, 2.5 MoM   | <u>Stability</u><br>Refrigerated – 72 Hour(s), Frozen – 2 Month(s)   |  |
| 1470             | Beryllium-Induced Lymphocyte Proliferation                                       | <u>Stability</u><br>Ambient – 48 Hour(s)   |  |
| 4114             | Carbamazepine  | <u>Stability</u><br>Ambient – 7 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)   |  |
| 3123R            | Cholinesterase RBC   | <u>Stability</u><br>Ambient – 72 Hour(s), Refrigerated – 72 Hour(s)  |  |
| 1610             | Complement C5  | <u>Reference Range</u><br>90-172 mg/L<br>(previously 67-175 mg/L)  |  |
| 1156             | Cryoglobulin   | <u>Preliminary Report</u><br>Detected or Not Detected at 72 hours<br>[final report remains Detected or Not Detected at 7 days]   | 1151- Cryofibrinogen<br>1158 - Cryoglobulin and Cryofibrinogen<br>1155 - Cryoglobulin reflex to Cryoprecipitate Immunoglobulins                              |
| 8132             | Hepatitis B Virus Drug Resistance DetectR™                                       | <u>Alternate Specimen</u><br>5 (3) mL Plasma PPT; PPT Tube<br><u>Alternate Specimen Stability</u><br>Ambient – 48 Hour(s), Refrigerated – 48 Hour(s), Frozen – 2 Month(s)<br><u>Collection Instructions</u><br>Ship by overnight courier.  | 8134 Hepatitis B Virus GenotypR™<br>8144 Hepatitis B Virus Core/Precore Mutant DetectR™  |
| 1350             | HLA:B27 Typing   | <u>Name</u><br>Change to HLA-B27 by Flow Cytometry.<br><u>Reference Range</u><br>Not detected (Possible reported results: Not detected, Indeterminate, Detected)<br><u>Notes</u><br>HLA-B27 testing was performed by flow cytometry using anti-HLA-B27 mAb clone FD705.  |  |
| 7780B            | HTLV I/III Antibodies [IB] plus bands  | <u>Name</u><br>HTLV I/III Antibodies (Confirmation by LIA) plus bands<br><u>Method</u><br>Line ImmunoAssay (INNO-LIA)<br><u>Reference Range</u><br>Negative (Possible reported results: Negative, Indeterminate, Positive)   | 7780 HTLV I/III Antibodies (confirmation by LIA)] also 7780C and 7780T<br>7780BT and 7780CB<br>9899 (reflex) HTLV I/III EIA Antibodies reflex to LIA + bands |
| 1230             | Immune Complex Assay, Raji Cell  | <u>Specimen</u><br>Specimen: 1(0.5) mL Serum or Plasma<br><u>Collection Instructions</u><br>Split each specimen into 2 plastic vials and freeze within 1 hour of collection. Ship frozen on dry ice by <i>Specialty</i> or overnight courier. Please note any delay in freezing sample on the requisition/order. If specimens are stored for longer periods, freeze at – 70 °C or below. |  |
| 3125U            | Monoclonal Gammopathies Urine  | <u>Specimen</u><br>4 (2) mL urine  |  |

|      |   |   |   |
|------|---|---|---|
| 4020 | Motor and Sensory Neuropathy Evaluation | <u>Method Change</u><br>Neuronal Nuclear (Hu) Autoabs now by IB   | 4021 Motor & Sensory Neuropathy EvaluatR™   |
|      |   | <u>Reference Range</u><br>Not Detected  | 4030 Sensory Neuropathy EvaluatR™   |
| 9721 | Mumps IgM Antibodies                    | <u>Reference Range (Interpretation)</u><br>< 0.80 Negative<br>0.80 – 1.19 Equivocal<br>> 1.19 Positive  | 4031 Sensory Neuropathy Eval<br>9711 Mumps IgG & IgM Antibodies   |
| 1491 | Plasminogen, Quantitative               | <u>Alternate Specimen/Stability</u><br>Specimen 1 (0.5) mL Plasma EDTA; Lavender Frozen – 2 Month(s)<br>Specimen 1 (0.5) Serum Refrigerated – 8 Day(s), Frozen – 2 Month(s)   | 2772 Meningoencephalitis (MEM) Panel  |
| 3218 | Sex Hormone Binding Globulin (SHBG)     | <u>Stability</u><br>Ambient – 7 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)  |   |
| 5945 | Thrombocytopenia, Heparin-Induced       | <u>Name</u><br>Change to Heparin-PF4 Antibodies (HIT)<br><u>Specimen/Stability</u><br>Primary Specimen: 1 (0.5) mL Serum; Frozen – 2 Month(s)<br>Alternate Specimen: 1 (0.5) mL Plasma Citrated Frozen – 2 Month(s) |   |
| 3238 | Thyroxine Binding Globulin              | <u>Stability</u><br>Ambient – 7 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)  |   |
| 3255 | Thyroglobulin Serum                     | <u>Stability</u><br>Ambient – 5 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)  | 3251 Thyroglobulin Evaluation   |
| 7666 | <i>Toxoplasma</i> IgA Antibodies        | <u>Reference Range (Interpretation)</u><br>Negative (Possible reported results: Negative, Equivocal, Positive)  | 2261 <i>Toxoplasma</i> Antibody Evaluation  |
| 7675 | <i>Toxoplasma</i> IgM Antibodies        | <u>Reference Range (Interpretation)</u><br>Negative (Possible reported results: Negative, Equivocal, Positive)  | 2261 <i>Toxoplasma</i> Antibody Eval<br>9901 TORCH IgG & IgM Abs Eval<br>2231 TORCH IgM Antibodies Eval |

## Discontinued Tests

**Effective Tuesday, October 26, 2004 or as noted**

The following test(s) are no longer routinely available from *Specialty*. Whenever possible, alternate tests are recommended. Please note that if a test is designated as a “replacement,” contractual pricing will be copied from discontinued test to replacement test. Contractual pricing does not apply to alternate tests or sendout tests. Please contact Client Services or your Sales Representative if you have any questions.

| Test Code | Test Name   | Reason                    | Alternate or Replacement Tests                              |
|-----------|---|---------------------------|---|
| 3143F     | Beta-2 Microglobulin Fluid                          | Low volume                | No Recommendation   |
| 1020F     | Complement Evaluation Fluid                         | Low volume                | No Recommendation   |
| 1501F     | Complement C3, Fluid                                | Low volume                | No Recommendation   |
| 1504F     | Complement C4, Fluid                                | Low volume                | No Recommendation   |
| 1511F     | Complement Factor B Fluid                           | Low volume                | No Recommendation   |
| S50004    | Creutzfeldt-Jacob 14-3-3                            | Ag is no longer available | No Recommendation   |
| 1506F     | IgA Fluid   | Low volume                | No Recommendation   |
| 1505F     | IgG Fluid   | Low volume                | No Recommendation   |
| 1508F     | IgM Fluid   | Low volume                | No Recommendation   |
| S50351    | Interleukin 12 serum/plasma<br>(effective 11-09-04) | In-house test available   | 3182 Interleukin 12, Serum<br>3182PL Interleukin 12, Plasma |
| S48790    | Metanephrines, plasma (effective 11-09-04)          | In-house test available   | 3317 Metanephrines, Plasma Free                             |

The following Allergen Panels have also been replaced by a new series of Regional Allergen Respiratory Panels which may be ordered with test #1245 Total IgE

Prior Allergen Panels

3716 Allergen Midwest Panel  
3717 Allergen Midwest Panel plus IgE  
3712 Allergen Northern California Panel  
3713 Allergen Northern California Panel plus IgE  
3720 Allergen Southeast Panel  
3721 Allergen Southeast Panel plus IgE  
3710 Allergen Southern California Panel  
3711 Allergen Southern California Panel plus IgE  
3714 Allergen Southwest Panel  
3715 Allergen Southwest Panel plus IgE  
3722 Allergen West Coast Panel  
3723 Allergen West Coast Panel plus IgE

New Allergen Panels

3724 Allergen Respiratory Panel 1 North Atlantic Region (CT, MA, NJ, PA, VT, ME, NH, NY, RI)  
3725 Allergen Respiratory Panel 2 Mid-Atlantic Region (DE, MD, VA, DC, NC)  
3726 Allergen Respiratory Panel 3 South Atlantic Region (GA, SC, Northern FL)  
3727 Allergen Respiratory Panel 4 Subtropical Florida Region (South of Orlando)  
3728 Allergen Respiratory Panel 5 Greater Ohio Valley Region (IN, OH, WV, KY, TN)  
3729 Allergen Respiratory Panel 6 South Central Region (AL, LA, AR, MS)  
3730 Allergen Respiratory Panel 7 Northern Midwest Region (MI, WI, MN)  
3731 Allergen Respiratory Panel 8 Central Midwest Region (IL, MO, IA)  
3732 Allergen Respiratory Panel 9 Great Plains Region (KS, NE, ND, SD)  
3733 Allergen Respiratory Panel 10 Southwestern Grassland Region (OK and TX)  
3734 Allergen Respiratory Panel 11 Rocky Mountain Region (AZ [Mtn], ID [Mtn], NM, WY, CO, MT, UT)  
3735 Allergen Respiratory Panel 12 Arid Southwest Region (Southern AZ and Southeast CA)  
3736 Allergen Respiratory Panel 13 Southern Coastal California Region  
3737 Allergen Respiratory Panel 14 Central California Valley Region  
3738 Allergen Respiratory Panel 15 Intermountain West Region (Nevada & Southern ID)  
3739 Allergen Respiratory Panel 16 Inland Northwest Region (Central and Eastern WA and OR)  
3740 Allergen Respiratory Panel 17 Cascade Pacific Northwest Region (NWest CA, Western OR, WA)  
3741 Allergen Respiratory Panel 18 Alaska

**For additional information please call Client Services at 800-421-4449  
or visit our Web site at [www.specialtylabs.com](http://www.specialtylabs.com)**