

# Lab Updates

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November 2009

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**UMassMemorial**

*Laboratories*

# Specific Immunoglobulin E (IgE) Allergen Tests

Allergic diseases are manifested as hyper responsiveness in the target organ, whether skin, nose, lung or GI tract. Most tests for “allergy” are actually tests for allergic sensitization, or the presence of allergen-specific IgE. Most patients who experience symptoms upon exposure to an allergen have demonstrable IgE that specifically recognizes that allergen, making these tests essential tools in the diagnosis of allergic disorders.

The demonstration of sensitization is not sufficient to diagnose an allergy, however, because a sensitized individual may be entirely asymptomatic upon exposure to the allergen in question. Thus, allergy tests must be interpreted in the context of the patient’s specific clinical history, and the diagnosis of an allergic disorder cannot be based solely on a laboratory result. This is true for in vitro assays, as well as for skin testing.

*In vitro* testing for allergy has certain advantages:

- It poses no risk to the patient of an allergic reaction.
- It is not affected by medications (antihistamines etc) the patient may be taking.
- It is not reliant upon skin integrity or affected by skin disease.
- It can be more convenient for the patient. In vitro testing requires submitting a blood sample and does not necessitate a separate visit for skin testing.



Photo: Kevin Vance

## UMass Memorial Medical Center Laboratories

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The most commonly-used in vitro tests in hospital and commercial laboratories are immunoassays. Immunoassays are often incorrectly referred to collectively as “RAST tests,” because radioactive tests were the earliest immunoassays to be used extensively.

Immunoassays are both qualitative and quantitative. The best documented and validated systems are those reporting quantitative results in kUA/L for IgE directed against specific allergens, using calibrators traceable to the WHO International Reference Preparation for human IgE. Testing systems that report values in these units are preferable to those reporting results in other units. Results are additionally graded into classes (typically I to IV or I to VI) based upon arbitrary divisions of a reference curve. If the result is markedly positive (eg, a Class VI result), the history suggests a past reaction to the allergen, and the allergen is well-characterized, then the diagnosis of an allergy can usually be made without further evaluation. If the result is weakly positive, then further evaluation is usually needed. Skin testing and possible challenge may be indicated, based upon the patient’s clinical history. A negative immuno-assay result in the setting of a strongly suggestive history does NOT exclude allergy. In this situation, a skin prick test should be considered (if not contraindicated).

False positive results of allergen-specific IgE can theoretically occur in patients with extremely elevated total IgE levels. Tests used largely in research settings include immunoblotting, basophil histamine or leukotriene release tests, basophil activation, and levels of eosinophil mediators etc, are not standardized, and are generally not superior to skin testing, and cannot be recommended for routine clinical use. Allergen-specific IgG and IgG4 tests, which are believed to correlate with normal immunologic responses to foreign substances, are not useful in the diagnosis of IgE-mediated allergy, with the exception of venom allergy. Unreliable testing methods include provocation/neutralization tests, kinesiography, cytotoxic tests, and electro dermal testing.

UMass Memorial Laboratories uses quantitative “ImmunoCAP” methodology for the measurement of allergen specific IgE in serum. Its clinical performance expressed as sensitivity ranging from 84-95% and specificity ranging from 85-94% has been reported from different multicenter studies for a wide range of different allergens. No changes in specimen collection requirements (SST, Serum). One full SST tube can perform up to 20 individual allergens. Please find below various types specific panels, mixes as well as specific allergen tests currently performed.

## Allergen Panel/Profiles (Immunoglobulin IgE)

| APAD Adult Food Profile |                      |
|-------------------------|----------------------|
| Mnemonic                | Test Name            |
| AF207                   | Clam                 |
| AF3                     | Codfish              |
| AF8                     | Corn                 |
| AF1                     | Egg White            |
| AF2                     | Milk                 |
| AF13                    | Peanut               |
| AF338                   | Scallop              |
| AF10                    | Sesame Seed          |
| AF24                    | Shrimp               |
| AF14                    | Soybean              |
| AF256                   | Walnut English/Black |
| AF4                     | Wheat                |
| IGE                     | IGE, Total           |

| APRE Respiratory Profile |                              |
|--------------------------|------------------------------|
| Mnemonic                 | Test Name                    |
| AG2                      | Bermuda Grass                |
| AE1                      | Cat Dander Epithelium        |
| AI6                      | Cockroach                    |
| AW1                      | Common Ragweed               |
| AE5                      | Dog Dander                   |
| AT8                      | Elm                          |
| AD2                      | House Dust Mite (D. Farinae) |
| AW10                     | Lamb’s Quarter               |
| AT1                      | Maple (Box Elder) Tree       |
| AM6                      | Mold (Alternaria Tenuis)     |
| AM2                      | Mold (Cladosporium Herbarum) |
| AT7                      | Oak                          |
| AG6                      | Timothy Grass                |
| IGE                      | IGE, Total                   |

## Allergen Panel/Profiles (Immunoglobulin IgE)

### APAS Asthma Profile

| Mnemonic | Test Name                          |
|----------|------------------------------------|
| AE1      | Cat Dander Epithelium              |
| AI6      | Cockroach                          |
| AW1      | Common Ragweed                     |
| AE5      | Dog Dander                         |
| AW9      | English Plantain                   |
| AD2      | House Dust Mite (D. Farinae)       |
| AD1      | House Dust Mite (D. Pteronyssinus) |
| AM6      | Mold (Alternaria Tenuis)           |
| AM5      | Mold (Candida Albicans)            |
| AM2      | Mold (Cladosporium Herbarum)       |
| AM4      | Mold (Mucor Racemosus)             |
| AM1      | Mold (Pencillium Notatum)          |
| AT7      | Oak                                |
| AG6      | Timothy Grass                      |
| IGE      | IGE, Total                         |

### ANUT Nut Profile

| Mnemonic | Test Name             |
|----------|-----------------------|
| AF20     | Almond                |
| AF18     | Brazil Nut            |
| AF202    | Cashew                |
| AF17     | Hazelnut              |
| AF13     | Peanut                |
| AF201    | Pecan Nut             |
| AF253    | Pine Nut Pignoles IGE |
| AF203    | Pistachio IGE         |
| AF256    | Walnut English/Black  |
| IGE      | IGE, Total            |

### APCH Childhood profile

| Mnemonic | Test Name                    |
|----------|------------------------------|
| AE1      | Cat Dander Epithelium        |
| AF3      | Codfish                      |
| AF8      | Corn                         |
| AE5      | Dog Dander                   |
| AF1      | Egg White                    |
| AD2      | House Dust Mite (D. Farinae) |
| AF2      | Milk                         |
| AM6      | Mold (Alternaria Tenuis)     |
| AM1      | Mold (Pencillium Notatum)    |
| AF13     | Peanut                       |
| AF14     | Soybean                      |
| AF4      | Wheat                        |
| IGE      | IGE, Total                   |

### ANEP Northeastern Pollen

| Mnemonic | Test Name            |
|----------|----------------------|
| AG17     | Bahia Grass          |
| AG2      | Bermuda Grass        |
| AT3      | Birch                |
| AT57     | Cedar/Red Tree       |
| AW14     | Common Pigweed IGE   |
| AT8      | Elm                  |
| AW9      | English Plantain     |
| AT4      | Hazelnut Tree        |
| AT41     | Hickory White        |
| AG8      | June (Kentucky Blue) |
| AW6      | Mugwort              |
| AW20     | Nettle               |
| AT7      | Oak                  |
| AW2      | Western Ragweed      |
| AT15     | White Ash IGE        |
| IGE      | IGE, Total           |

## Allergen Mix Menu

| Mnemonic | Mix Name     | Mix Composition   |
|----------|--------------|---|
| AEP1     | Animal Mix 1 | Cat Dander Epithelium, Cow Dander, Dog Dander, Horse Dander   |
| AFP1     | Food Mix 1   | Almond, Brazil Nut, Coconut, Hazelnut, Peanut   |
| AFP2     | Food Mix 2   | Blue Mussel, Cod Fish, Salmon, Shrimp, Tuna   |
| AFP3     | Food Mix 3   | Buck Wheat, Corn, Oat, Sesame Seed, Wheat   |
| AFP5     | Food Mix 5   | Cod Fish, Egg White, Milk, Peanut, Soybean, Wheat   |
| AGP1     | Grass Mix 1  | June (Kentucky Blue), Meadow Fescue, Orchard Grass, Perennial Rye Grass, Timothy Grass              |
| AGP2     | Grass Mix 2  | Bahia Grass, Bermuda Grass, Johnson Grass, June (Kentucky Blue), Perennial Rye Grass, Timothy Grass |
| AGP3     | Grass Mix 3  | Cultivated Rye Grass, Perennial Rye Grass, Timothy Grass, Sweet Vernal Grass, Velvet Grass          |
| AGP4     | Grass Mix 4  | Common Red Grass, Cultivated Rye Grass, Perennial Rye Grass, Sweet Vernal Grass, Velvet Grass       |
| AHP1     | Dust Mix 1   | Cockroach, D. Farinae, D. Pteronyssinus, Hollister-Stier  |
| AMP1     | Mold Mix     | Alternaria Tenuis, Aspergillus Fumigatus, Cladosporium Herbarum, Penicillium Notatum                |
| ATP1     | Tree Mix 1   | Birch, Elm, Maple, Oak, Walnut  |
| ATP2     | Tree Mix 2   | Cottonwood, Elm, Maple, Oak, Pecan  |
| ATP4     | Tree Mix 4   | Cottonwood, Elm, Oak, Sycamore, Willow  |
| ATP9     | Tree Mix 9   | Alder, Birch, Hazlenut, Oak, Willow   |
| AWP1     | Weed Mix 1   | Common Ragweed, English Plantain, Lamb's Quarter, Mugwort, Russian Thistle                          |
| AWP2     | Weed Mix 2   | English Plantain, Lamb's Quarter, Mugwort, Scale, Western Ragweed                                   |



## Specific Immunoglobulin E (IgE) Allergen Tests

### Allergen Class: Weeds

| Mnemonic | Allergen Test    |
|----------|------------------|
| AW13     | Cocklebur        |
| AW14     | Common Pigweed   |
| AW1      | Common Ragweed   |
| AW8      | Dandelion        |
| AW9      | English Plantain |
| AW3      | Giant Ragweed    |
| AW12     | Goldenrod        |
| AW10     | Lamb's Quarter   |
| AW6      | Mugwort          |
| AW20     | Nettle           |
| AW7      | Ox-Eye Daisy     |
| AW11     | Russian Thistle  |
| AW15     | Scale            |
| AW18     | Sheep Sorrel     |
| AW2      | Western Ragweed  |

### Allergen Class: House Dust

| Mnemonic | Allergen Test                |
|----------|------------------------------|
| AH1      | House Dust (Greer)           |
| AH2      | House Dust (Hollister-Stier) |

### Allergen Class: Mites

| Mnemonic | Allergen Test                               |
|----------|---|
| AD1      | House Dust Mite ( <i>D. Pteronyssinus</i> ) |
| AD2      | House Dust Mite ( <i>D. Farinae</i> )       |
| AD70     | House Dust Mite ( <i>Acarus Siro</i> )      |

### Allergen Class: Occupational

| Mnemonic | Allergen Test |
|----------|---------------|
| AK82     | Latex         |

### Allergen Class: Animals

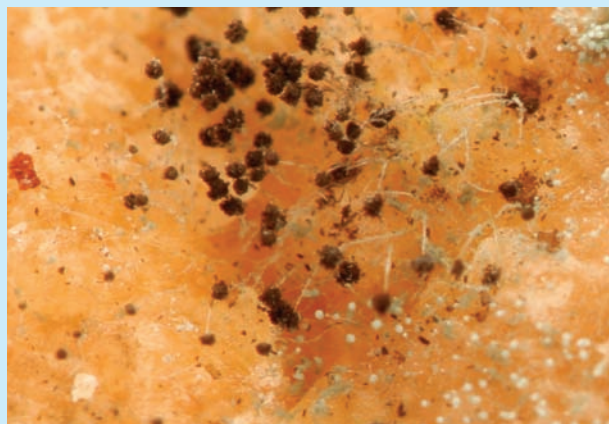
| Mnemonic | Allergen Test         |
|----------|-----------------------|
| AE1      | Cat Dander Epithelium |
| AE85     | Chicken Feathers      |
| AE4      | Cow Dander            |
| AE5      | Dog Dander            |
| AE2      | Dog Epithelium        |
| AE80     | Goat Epithelium       |
| AE70     | Goose Feathers        |
| AE6      | Guinea Pig Epithelium |
| AE84     | Hamster Epithelium    |
| AE3      | Horse Dander          |
| AE88     | Mouse                 |
| AE71     | Mouse Epithelium      |
| AE213    | Parrot Feathers       |
| AE82     | Rabbit Epithelium     |
| AE87     | Rat                   |
| AE73     | Rat Epithelium        |
| AE81     | Sheep Epithelium      |
| AE83     | Swine Epithelium      |



## Specific Immunoglobulin E (IgE) Allergen Tests

### Allergen Class: Molds

| Mnemonic | Allergen Test         |
|----------|-----------------------|
| AM6      | Alternaria Tenuis     |
| AM3      | Aspergillus Fumigatus |
| AM5      | Candida Albicans      |
| AM2      | Cladosporium Herbarum |
| AM16     | Curvularia Lunata     |
| AM14     | Epicoccum Purpurascen |
| AM9      | Fusarium Moniliforme  |
| AM8      | Helmin Halodes        |
| AM4      | Mucor Racemosus       |
| AM1      | Pencillium Notatum    |
| AM13     | Phoma Betae Mold      |
| AM12     | Pullularia Pullulans  |
| AM11     | Rhizopus Nigricans    |
| AM10     | Stemphylium Botryosum |



### Allergen Class: Grass

| Mnemonic | Allergen Test        |
|----------|----------------------|
| AG17     | Bahia Grass          |
| AG9      | Bent/Redtop Grass    |
| AG2      | Bermuda Grass        |
| AG7      | Common Reed Grass    |
| AG12     | Cultivated Rye Grass |
| AG10     | Johnson Grass        |
| AG8      | June (Kentucky Blue) |
| AG4      | Meadow Fescue        |
| AG3      | Orchard Grass        |
| AG5      | Perennial Rye Grass  |
| AG1      | Sweet Vernal Grass   |
| AG6      | Timothy Grass        |
| AG13     | Velvet Grass         |

### Allergen Class: Tree

| Mnemonic | Allergen Test          |
|----------|------------------------|
| AT19     | Acacia                 |
| AT2      | Alder                  |
| AT73     | Australian Pine        |
| AT5      | Beech                  |
| AT3      | Birch                  |
| AT212    | Cedar                  |
| AT57     | Cedar/Red Tree         |
| AT14     | Cottonwood             |
| AT8      | Elm                    |
| AT18     | Eucalyptus             |
| AT4      | Hazelnut Tree          |
| AT41     | Hickory White          |
| AT1      | Maple (Box Elder) Tree |
| AT21     | Melaleuca              |
| AT20     | Mesquite               |
| AT6      | Mountain Cedar         |
| AT7      | Oak                    |
| AT9      | Olive                  |
| AT22     | Pecan Tree             |
| AT11     | Sycamore               |
| AT10     | Walnut Tree            |
| AT15     | White Ash              |
| AT70     | White Mulberry         |
| AT16     | White Pine             |
| AT12     | Willow                 |

## Specific Immunoglobulin E (IgE) Allergen Tests



### Allergen Class: Foods

| Mnemonic | Allergen Test      |
|----------|--------------------|
| AF339    | Allspice           |
| AF20     | Almond             |
| AF76     | Alpha Lactalbumin  |
| AF49     | Apple              |
| AF237    | Apricot            |
| AF262    | Aubergine Eggplant |
| AF96     | Avocado            |
| AF45     | Baker's Yeast      |
| AF92     | Banana             |
| AF6      | Barley             |
| AF269    | Basil              |
| AF278    | Bayleaf            |
| AF27     | Beef               |
| AF77     | Beta Lactoglobulin |
| AF280    | Black Pepper       |
| AF37     | Blue Mussel        |
| AF288    | Blueberry          |
| AF18     | Brazil Nut         |
| AF260    | Broccoli           |
| AF11     | Buck Wheat         |
| AF93     | Cacao              |
| AF31     | Carrot             |
| AF78     | Casein             |

### Allergen Class: Foods

| Mnemonic | Allergen Test      |
|----------|--------------------|
| AF202    | Cashew             |
| AF291    | Cauliflower        |
| AF85     | Celery             |
| AF81     | Cheese Cheddar     |
| AF242    | Cherry             |
| AF299    | Chestnut           |
| AF83     | Chicken Meat       |
| AF309    | Chickpea           |
| AF279    | Chili Pepper       |
| ARF220   | Cinnamon           |
| AF207    | Clam               |
| AF36     | Coconut            |
| AF3      | Codfish            |
| AF317    | Coriander/Cilantro |
| AF8      | Corn               |
| AF23     | Crab               |
| AF320    | Crayfish           |
| AF244    | Cucumber           |
| AF281    | Curry Powder       |
| AF277    | Dill               |
| AF1      | Egg White          |
| AF75     | Egg Yolk           |
| AF254    | Flounder Plaice    |
| AF47     | Garlic             |
| AF79     | Gluten             |
| AF259    | Grape              |
| AF209    | Grapefruit         |
| AF315    | Green Bean         |
| AF12     | Green Pea          |
| AF42     | Haddock            |
| AF303    | Halibut            |
| AF17     | Hazelnut           |
| AF287    | Kidney Bean        |
| AF84     | Kiwi Fruit         |
| AF208    | Lemon              |

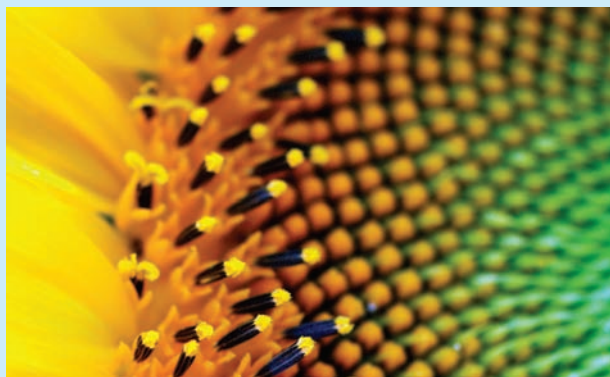
## Specific Immunoglobulin E (IgE) Allergen Tests

| Allergen Class: Foods |                      |
|-----------------------|----------------------|
| Mnemonic              | Allergen Test        |
| AF235                 | Lentil               |
| AF215                 | Lettuce              |
| AF306                 | Lime                 |
| AF80                  | Lobster              |
| AF345                 | Macadamia Nut        |
| AF90                  | Malt                 |
| AF91                  | Mango Fruit          |
| AF87                  | Melon                |
| AF2                   | Milk                 |
| AF212                 | Mushroom             |
| AF89                  | Mustard              |
| ARF282                | Nutmeg               |
| AF7                   | Oat                  |
| AF48                  | Onion                |
| AF33                  | Orange               |
| AF283                 | Oregano              |
| AF290                 | Oyster               |
| AF293                 | Papaya               |
| AF218                 | Paprika/Sweet Pepper |
| AF86                  | Parsley              |



| Allergen Class: Foods |                      |
|-----------------------|----------------------|
| Mnemonic              | Allergen Test        |
| AF95                  | Peach                |
| AF13                  | Peanut               |
| AF94                  | Pear                 |
| AF201                 | Pecan Nut            |
| AF253                 | Pine Nut Pignoles    |
| AF210                 | Pineapple            |
| AF203                 | Pistachio            |
| AF255                 | Plum                 |
| AF26                  | Pork                 |
| AF35                  | Potato               |
| AF343                 | Raspberry            |
| AF9                   | Rice                 |
| AF5                   | Rye                  |
| AF344                 | Sage                 |
| AF41                  | Salmon               |
| AF338                 | Scallop              |
| AF10                  | Sesame Seed          |
| AF24                  | Shrimp               |
| AF14                  | Soybean              |
| AF214                 | Spinach              |
| AF258                 | Squid                |
| AF44                  | Strawberry           |
| AF54                  | Sweet Potato         |
| AF312                 | Swordfish            |
| AF273                 | Thyme                |
| AF25                  | Tomato               |
| AF204                 | Trout                |
| AF40                  | Tuna                 |
| AF284                 | Turkey               |
| AF234                 | Vanilla              |
| AF256                 | Walnut English/Black |
| AF329                 | Watermelon           |
| AF4                   | Wheat                |
| AF236                 | Whey                 |
| AF15                  | White Bean           |

## Specific Immunoglobulin E (IgE) Allergen Tests



### Allergen Class: Miscellaneous

| Mnemonic | Allergen Test  |
|----------|----------------|
| IGE      | IGE, Total     |
| AK84     | Sunflower Seed |

### Allergen Class: Insects/Venoms

| Mnemonic | Allergen Test       |
|----------|---------------------|
| AI6      | Cockroach           |
| AI1      | Honey Bee Venom     |
| AI4      | Paper Wasp Venom    |
| AI2      | White Faced Hornet  |
| AI5      | Yellow Hornet       |
| AI3      | Yellow Jacket Venom |

If you have questions, comments or suggestions, please contact:  
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## Spurious Hyperbilirubinemia Caused by Naproxen

A metabolite of Naproxen, O-desmethylnaproxen (ODMN), has been shown to interfere with the measurements of total bilirubin. Naproxen, a derivative of naphthalene, is a commonly prescribed non steroidal anti-inflammatory drug (NSAID). In humans naproxen metabolites include the major metabolite ODMN, two distinct acyl glucuronide forms of the parent drug, and various ODMN conjugated acyl glucuronide forms. In the plasma most of the drug remains as unconjugated naproxen with unconjugated ODMN levels 100 times less than

those of naproxen. When evaluating high levels of total bilirubin from patients who have taken naproxen, the above interference should be considered.

If you have questions, comments or suggestions, please contact:  
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# Change in Cytomegalovirus Quantitative Testing

Umass Memorial Molecular lab is pleased to announce an increased sensitivity for our Cytomegalovirus Quantitative Assay (CMV). CMV is frequently used to monitor the effectiveness of anti-viral therapy in transplant patients and we believe this increase in sensitivity will help clinicians quantify and detect virus levels earlier.

**The sensitivity of the CMV assay has been increased** from 600 copies/ml to 50 copies/ml. The CMV quantitative analytical measurement range of this assay is now 50 - 4,200,000 CMV copies/ml of plasma.

In addition to the result being expressed in copy number per milliliter (ml), we have enhanced the reporting format to include additional information. The report will now indicate if the virus was “Detected”, “Not detected” or “Detected but below Quantitative range” in the sample.

Further explanation of this revised report interpretations are detailed below:

- a) “Detected” - means that the viral titer in the sample is above the lower limit of quantitation and **is** quantified;
- b) “Detected” - Not Quant” - means that the viral titer in the sample is below the lower limit of quantitation (LLOQ) but above the assay’s lower limit of detection (LLOD);
- c) “Not Detected” - means that the viral titer in the sample is below the assay’s lower limit of detection.

The only change is in the required volume of plasma which is needed to perform the assay. We will now require 3 ml of plasma in order to perform this assay and allow for repeat testing if necessary.

| Cytomegalovirus DNA by PCR, Quant (CMVPCR) |  |
|--|--|
| <b>Methodology:</b>                        | RT-Polymerase Chain Reaction   |
| <b>Performed:</b>                          | Varies   |
| <b>Reported:</b>                           | 5 Days   |
| <b>CPT:</b>                                | 87497  |
| Specimen Requirements                      |  |
| <b>Collect:</b>                            | PPT  |
| <b>Transport:</b>                          | Frozen   |
| <b>Min Volume:</b>                         | 3 mL Plasma  |
| <b>Notes:</b>                              | Spin PPT tube and place in refrigerator or freezer. Ensure there is a complete barrier protection between the plasma and the cells after spinning. Spin/separated plasma sample is stable for 6 hours refrigerated. If transport to the lab will be longer than 6 hours, freeze. |

In the event we receive less than 1.5 ml of plasma, the amount needed to perform the assay without repeats, we will still attempt to perform the assay. Please note that the lower sample volume will change the assay low end detection to 600 copies /ml not the increased range of 50 copies /ml.

**If you have questions, comments or suggestions, please contact:**

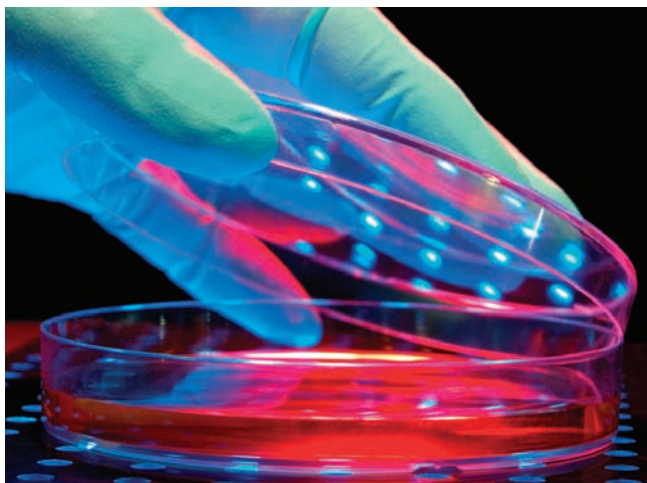
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# Sequencing Assay for Detecting Pompe Disease Mutations



Effective November 9, 2009, sequencing to detect mutations in the GAA (acid alpha-glucosidase) gene that cause Pompe disease (Glycogen Storage Disease Type II) will be available through the UMass Memorial Molecular Diagnostics Laboratory.

## Background:

Pompe disease is a rare autosomal recessive inherited disorder caused by a deficiency of acid alpha-glucosidase. This enzyme deficiency leads to an accumulation of lysosomal glycogen in smooth, skeletal, and cardiac muscles. The disorder is classified into three clinically distinct subtypes. Infantile-onset Pompe disease most often presents in the first month of life with hypotonia, failure to thrive and hypertrophic cardiomyopathy. Juvenile onset Pompe disease usually presents in the first year of life with motor delays and generalized muscle weakness, but without cardiomyopathy. The late onset form of Pompe disease typically presents in the third decade of life with generalized muscle weakness. Enzyme replacement therapy (ERT) is available to treat affected individuals.

Pompe disease has an incidence of 1:40,000 in the general population. Molecular analysis of the GAA gene is important for diagnosis of Pompe disease so that proper management decisions are made for affected individuals. Additionally, molecular diagnosis provides information to families with an affected individual (i.e. prenatal diagnosis, carrier screening in relatives).

Over 100 disease-causing GAA mutations have been identified thus far. Sequencing of 20 exons of this gene detects up to 99% of affected alleles. GAA sequencing is indicated for individuals with symptoms of Pompe disease, individuals who are known to have deficient GAA enzyme activity, and individuals who have a family history of Pompe disease.

## Methodology:

Sequencing is performed via polymerase chain reaction (PCR) amplification and is followed by double-stranded DNA sequence analysis using capillary electrophoresis.

This sensitive analysis of the GAA gene may result in the discovery of genetic variants of uncertain clinical significance. When these variants are discovered, they will be reported as such.

## Requirements:

The UMass Memorial Molecular Diagnostics Test Requisition should be used and sent with the sample. Informed consent is required for carrier testing of unaffected family members. Copies of this requisition and consent forms may be obtained from Customer Service at (800)476-4431. Specimen requirement is 3 milliliter of blood in a lavender top (EDTA) tube, sent to the laboratory either at room temperature or refrigerated (not frozen). TAT – 4 weeks.

## References:

1. Hermans M, van Leenen D, Kroos M, et. al. “Twenty-Two Novel Mutations in the Lysosomal -Glucosidase Gene (GAA) Underscore the Genotype-Phenotype Correlation in Glycogen Storage Disease Type II”. *Human Mutation* (2004) 23: 47-56.
2. Database of Pompe mutations at [www.pompecenter.nl](http://www.pompecenter.nl).

## If you have questions, comments or suggestions, please contact:

Dr. Edward Ginns at 508-856-8134 or via email at [Edward.Ginns@umassmed.edu](mailto:Edward.Ginns@umassmed.edu)

Dr. Marzena Galdzicka at 508-856-4384 or via email at [Marzena.Galdzicka@umassmed.edu](mailto:Marzena.Galdzicka@umassmed.edu)

# HBV Quantitation by PCR (COBAS® TaqMan®)

**Beginning November 9, 2009**, the UMass Memorial Molecular Diagnostics Laboratory will begin offering quantitative testing for the HBV viruses using the COBAS® AmpliPrep and COBAS® TaqMan® system.

This quantitative assay is intended for use as an aid in the management of individuals already known to be infected with HBV. This test can be used in conjunction with other clinical and laboratory findings to measure baseline viral levels and for monitoring the effects of antiretroviral treatment. The COBAS® TaqMan® HBV Test is not intended for use as a screening test for blood or blood products for the presence of HBV, or as a diagnostic test to confirm the initial presence of HBV infection.

The analytical measurement range of this assay without any dilution is 29 to 1.1E+08 IU/ml (1.46 and 8.04 log IU/ml). The clinically reportable range of this assay with a dilution of one to one-hundred is 29 to 1.1E+10 IU/ml (1.46 and 10.04 log IU/ml).

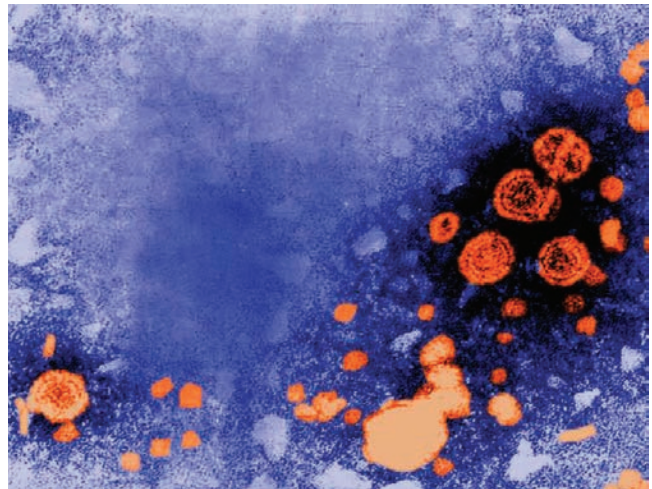
### Sensitivity:

The lower limit of quantitation (LLOQ) of the Cobas TaqMan HBV assay is 29 IU/ml (1.46 log IU/ml) and the lower limit of detection (LLOD) of this assay is 10 IU/ml (1 log IU/ml).

### Results Reporting:

In addition to the result being expressed in the copy number per milliliter (copy/ml), international units per milliliter (IU/ml) and log IU/ml, the report will interpret if the virus was “Detected”, “Not detected” or “Detected - Not Quant” in the tested sample. More details of this report interpretation are:

- a) “Detected” - means that the viral titer in the sample is above the lower limit of quantitation;
- b) “Detected - Not Quant” - means that the viral titer in the sample is below the lower limit of quantitation (LLOQ) but above the assay’s lower limit of detection (LLOD);
- c) “Not Detected” – means that the viral titer in the sample is below the assay’s lower limit of detection.



Courtesy of Department of Health and Human Services Public Health Image Library (PHIL)

The conversion factor between HBV copies/ml and HBV IU/ml is 5.82 copies/IU using the WHO International Standard for Hepatitis B Virus DNA for Nucleic Acid technology (NAT) Assays Tasting NIBSC 97/746.

### Limitations:

This test is not intended for use as a diagnostic test to confirm the initial presence of HBV infection. A result of “Not Detected” does not rule out the presence of HBV that is not detectable for reasons such as PCR inhibitors or viral concentrations below the detection levels of the assay. In addition, this test may cross-react with HPV Type 18 and CMV.

### Methodology:

The COBAS® system test is a diagnostic platform assay that utilizes automated specimen preparation followed by automated PCR amplification and detection of cleaved dual-labeled detection probes specific to the HBV target DNA.

### If you have comments, questions, or suggestions, please contact:

Dr. Edward Ginns at 508-856-8134, or via email at [Edward.Ginns@umassmed.edu](mailto:Edward.Ginns@umassmed.edu)

Dr. Marzena Galdzicka at 508-856-4384 or via email at [Marzena.Galdzicka@umassmed.edu](mailto:Marzena.Galdzicka@umassmed.edu)

| Ordering Mnemonic | Test Name                       | Sample Type   |
|-------------------|---------------------------------|---|
| HEPBPCR           | Hepatitis B Quantitation by PCR | Draw 1 full PPT tube. Spin PPT tube within 4 hours ensuring there is complete barrier protection between the plasma and the cells after spinning. Place the spun sample in either the refrigerator or freezer. Sample is stable Refrigerated: 24 hours; Frozen (-20°C): 3 days; Frozen (-70°C): 4 months. <b>Minimum sample:</b> 2.5 ml plasma. <b>Turnaround Time:</b> 3-5 days. |

# Enterovirus Detection Assay by Real Time PCR

**Beginning November 9, 2009**, the UMass Memorial Molecular Diagnostics Laboratory will begin offering a new Enterovirus qualitative assay by Real Time PCR. This assay determines the presence or absence of Enterovirus nucleic acid target sequence using fluorescent based PCR chemistry.

## Sensitivity:

The lower limit of detection of this assay is 400 copies/ml.

## Limitations:

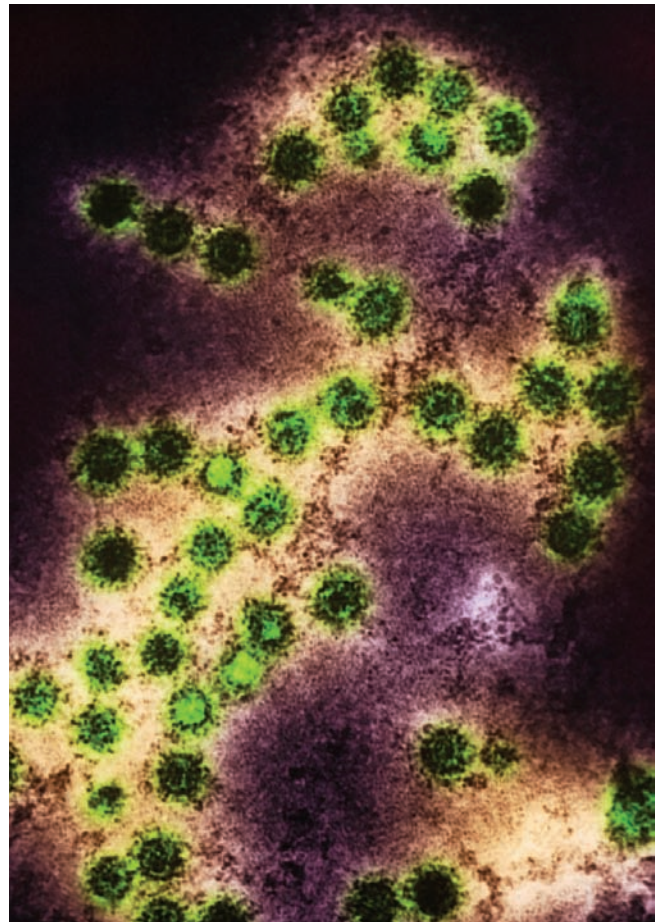
The result “Not Detected” does not rule out the presence of enterovirus that is not detectable for reasons such as PCR inhibitors or viral concentrations below the detection levels of the assay.

Cross-reactivity with any rhinoviruses cannot be completely excluded due to their close homology with enteroviruses. The presence of rhinovirus in CSF is unlikely, but sufficient care should be taken during specimen collection and processing to avoid contaminating the sample with rhinoviruses from other sources.

## Methodology:

The Enterovirus detection assay is performed following the isolation of Enterovirus RNA from Cerebrospinal fluid (CSF), urine, stool, plasma or other specimen using reverse transcription, followed by real-time PCR. The assay amplifies nucleic acid from the 5' untranslated region (UTR) specific to multiple prevalent enteroviral strains. The primers in this assay were tested to detect the following serotypes of Enterovirus: Echo 4, 6, 9, 11 and 30, Polio 1, 2, and 3, Coxsakie A9, and Coxsakie B1, B2, B3, B5 and B6. Due to their divergent genome sequences, this test does not detect echoviruses 22 and 23, which have recently been reclassified as parechovirus. Current classification of Enteroviruses is shown in table below.


|   |
|---|
| <b>Human Enterovirus A (HEV-A)</b>  |
| CAV2-8, 10, 12, 14, 16; EV71, EV76, EV89, EV90, EV91                                  |
| <b>Human Enterovirus B (HEV-B)</b>  |
| CAV9; CBV1-6; E1-7, 9, 11-21, 24-27, 29-33, EV69, EV73-75, EV77-8, EV79-88, EV100-101 |
| <b>Human Enterovirus C (HEV-C)</b>  |
| CAV1, 11, 13, 17, 19-22, 24, PV1-3  |
| <b>Human Enterovirus D (HEV-D)</b>  |
| EV68,70   |



\*Enteroviruses 79-101 are not yet included in the International Committee on Taxonomy of Viruses classification. The gaps in numbering result from changes in classification. Since the time of their discovery and initial classification, some serotypes have been found to be identical to one another (i.e., coxsackievirus A15 is the same as coxsackievirus A11, coxsackievirus A18 is the same as coxsackievirus A13, coxsackievirus A23 is the same as echovirus 9, echovirus 8 is the same as echovirus 1, and echovirus 34 has been reclassified as Cox A24 variant and Echo 10 is reovirus 1 (genus Orthoreovirus, family Reoviridae), echovirus 28 is human rhinovirus 1A (genus Rhinovirus, family Picornaviridae), echovirus 72 is human hepatitis A virus (genus Hepatovirus, family Picornaviridae), and echoviruses 22 and 23 are now considered human parechoviruses 1 and 2, respectively (genus Parechovirus, family Picornaviridae).

## Turnaround Time:

3-5 days

| Ordering Mnemonic   | Test Name                          | Sample Type  |
|---|------------------------------------|--|
| ENTEROV – for CSF<br><br> | Enterovirus Detection<br>by RT-PCR | <p><b>Collection:</b> CSF in a sterile container</p> <p><b>Transport:</b> Frozen CSF</p> <p><b>Pediatric Collection/Transport:</b> Minimum of 0.5 ml CSF in a sterile container. (Smaller volume will decrease sensitivity of the assay.)</p> <p><b>Unacceptable Conditions:</b> Non-frozen specimens, specimens exposed to repeated freeze/thaw cycles, nonsterile or leaking containers</p> <p><b>Stability:</b> Ambient: 1 hour; Refrigerated: 24 hours; Frozen: 3 months</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>If you have questions, comments or suggestions, please contact:</b><br/>           Dr. Michael Mitchell at 774-442-9630 or via email at <a href="mailto:Michael.Mitchell@umassmemorial.org">Michael.Mitchell@umassmemorial.org</a><br/>           Dr. Edward Ginns at 508-856-8134 or via email at <a href="mailto:Edward.Ginns@umassmed.edu">Edward.Ginns@umassmed.edu</a><br/>           Dr. Marzena Galdzicka at 508-856-4384 or via email at <a href="mailto:Marzena.Galdzicka@umassmed.edu">Marzena.Galdzicka@umassmed.edu</a></p> </div> |



# UMass Memorial Laboratories Patient Service Center Locations

## Worcester PSC Locations

### Belmont Street PSC

67 Belmont Street  
Worcester, MA 01605  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-334-5396

### City Hospital Campus PSC

26 Queen Street, 1st Floor  
Worcester, MA 01610  
Mon–Fri 8:00am - 5:00pm  
Closed 12:00pm - 1:00pm  
508-334-7881

### Grove Medical PSC

26 Queen Street, 6th Floor  
Worcester, MA 01610  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-334-0275

### Hahnemann Professional PSC

291 Lincoln Street  
Worcester, MA 01605  
Mon–Fri 8:00am - 5:00pm  
508-792-8208

### Lincoln Street PSC

121 Lincoln Street, Unit 13  
Worcester, MA 01605  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-751-4685

### Medical Office Building

25 Oak Avenue  
Worcester, MA 01605  
Mon–Fri 8:00am - 5:00pm  
508-792-3656

### Medical Office Building PSC

116 Belmont Street  
Worcester, MA 01605  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-753-6854

### Park Avenue PSC

255 Park Avenue  
Suite 210  
Worcester, MA 01609  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-798-5127

### Plantation Street PSC

338 Plantation Street  
Worcester, MA 01604  
Mon–Fri 8:30am - 5:00pm  
Closed 12:00pm - 1:00pm  
508-755-4896

### UMass Memorial-Hahnemann Campus

281 Lincoln Street  
Worcester, MA 01605  
Mon–Fri 7:00am - 5:30pm  
508-334-8100

### UMass Memorial-Memorial Campus

119 Belmont Street  
Worcester, MA 01605  
Mon–Fri 7:00am - 6:00pm  
Sat & Sun 8:00am - 1:00pm  
508-334-6486

### UMass Memorial-University Campus

55 Lake Avenue North  
Worcester, MA 01655  
Mon–Fri 7:30am - 5:30pm  
508-856-7797

### Vernon Medical Center PSC

10 Winthrop Street  
Building #2, 1st Floor  
Worcester, MA 01604  
Mon–Fri 8:00am - 5:00pm  
508-831-0624

### West Boylston Street PSC

1 West Boylston Street  
Worcester, MA 01605  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-853-1208

## Central Massachusetts Locations

### Clinton PSC

Clinton Hospital  
201 Highland Street  
2nd Floor, Suite 1  
Mon & Wed 8:00am - 5:30pm  
Tues, Thurs & Fri 8:00am - 5:00pm  
Closed 1:00pm - 1:30pm  
Clinton, MA 01510  
978-368-3704

### Douglas PSC

15 West Street  
Douglas, MA 01516  
Mon–Fri 8:00am - 12:00pm  
508-476-2365

### Fitchburg PSC

HealthAlliance/Burbank Hospital Campus  
275 Nichols Street, 4th Floor  
Fitchburg, MA 01420  
Tues, Wed, & Thurs 8:30am - 9:00pm  
Mon & Fri 8:30am - 5:30pm  
978-878-8352

### Holden PSC

52 Boyden Street  
Holden, MA 01520  
Mon–Fri 7:00am - 4:30pm  
Closed 12:30pm - 1:00pm  
508-829-8262

### Lancaster PSC

136 High Street Ext  
Lancaster, MA 01523  
Mon–Fri 8:00am - 5:00pm  
Closed 12:00pm - 1:00pm  
978-368-1683

### Marlborough/Bolton Street PSC

320 Bolton Street, Suite G1  
Marlborough, MA 01752  
Mon–Fri 8:00am - 5:00pm  
Closed 11:15am - 12:15pm  
508-229-0574

# UMass Memorial Laboratories Patient Service Center Locations

## Central Massachusetts Locations

### Marlborough/Lakeview PSC

640 Bolton Street  
Marlborough, MA 01752  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-303-1990

### Marlborough/Maple Street PSC

340 Maple Street  
Marlborough, MA 01752  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-229-7847

### Milford PSC

91 Water Street  
Milford, MA 01757  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-482-9210

### Northborough PSC

112 Main Street  
Northborough, MA 01532  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-393-3704

### Rutland PSC

54B Maple Avenue  
Mon–Fri 8:00am - 5:00pm  
Closed 12:00pm - 1:00pm  
Rutland, MA 01543  
508-886-7480

### Shrewsbury/Julio Drive PSC

26 Julio Drive  
Shrewsbury, MA 01545  
Mon–Fri 8:00am - 5:00pm  
Closed 12:00pm - 1:00pm  
508-845-3615

### Shrewsbury/Main Street PSC

604 Main Street  
Shrewsbury, MA 01545  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-845-6521

### Sterling PSC

104 Leominster Road  
Sterling, MA 01564  
Mon–Fri 8:00am - 5:00pm  
978-422-5109

### Westborough/East Main Street PSC

33 East Main Street  
Westborough, MA 01581  
Mon–Fri 8:00am–5:00pm  
Closed 12:15–1:15pm  
508-366-2838

### Westborough/Main Street PSC

154 Main Street  
Westborough, MA 01581  
Mon 7:30am - 5:00pm  
Tues–Thurs 8:30am - 5:00pm  
Fri 7:00am - 4:00pm  
Closed 12:30pm - 1:30pm  
508-836-3674

## Eastern Massachusetts Locations

### Brockton PSC

1073 Pleasant Street  
Brockton, MA 02301  
Mon–Fri 8:00am - 5:00pm  
508-559-2158

### Dartmouth PSC

72 State Road  
Dartmouth, MA 02747  
Mon–Fri 7:00am - 4:00pm  
Closed 12:00pm - 1:00pm  
Sat 7:00am - 11:00am  
508-997-4132

### Dorchester/Harvard Street PSC

632 Blue Hill Avenue  
Dorchester, MA 02121  
Mon & Wed 8:30am - 8:30pm  
Tues, Thurs & Fri 8:30am - 5:30pm  
617-822-5523

### Framingham PSC

61 Lincoln Street, 2nd Floor  
Framingham, MA 01702  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-370-7259

### Hyannis PSC

700 Attucks Lane, Suite 1D  
Hyannis, MA 02601  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
508-790-5723

### North Andover/Chestnut Green Turnpike Street PSC

565 Turnpike Street, Suite 83  
North Andover, MA 01845  
Mon–Fri 8:30am - 5:30pm  
Closed 12:15pm - 1:15pm  
978-989-9472

### North Andover/Andover Street PSC

451 Andover Street, Suite 206  
North Andover, MA 01845  
Mon–Thurs 7:30am - 4:30pm  
Fri 7:00am - 4:00pm  
Closed 12:15pm - 1:15pm  
978-989-9238

### Raynham PSC

675 Paramount Drive, Suite 102  
Raynham, MA 02767  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
Sat 8:00am - 1:00pm  
508-824-0838

# UMass Memorial Laboratories Patient Service Center Locations

## Eastern Massachusetts Locations

**Waltham/Hope Avenue PSC**  
20 Hope Avenue, Suite G03  
Waltham, MA 02453  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
**781-899-2586**

**Waltham/Lexington Street PSC**  
6 Lexington Street, 2nd Floor  
Waltham, MA 02453  
Mon–Fri 8:00am - 4:30pm  
Closed 12:00pm - 12:30pm  
**781-647-0352**

**Wilmington PSC**  
64 Concord Street, Suite D  
Wilmington, MA 01887  
Mon–Fri 8:30am - 5:00pm  
Closed 12:15pm - 12:45pm  
**978-694-1581**

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## Western Massachusetts Locations

**Springfield PSC**  
3640 Main Street, Suite 202  
Springfield, MA 01107  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
**413-732-5027**

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## Connecticut Locations

**Branford/Stony Creek PSC**  
6 Business Park Dr Suite 203  
Branford, CT 06405  
Mon–Fri 7:30am - 4:00pm  
**203-315--4907**

**East Hartford PSC**  
580 Burnside Avenue  
Suite 1  
East Hartford, CT 06108  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
**860-610-0386**

**Enfield PSC**  
Enfield Professional Park  
139A Hazard Avenue  
Building #4, Suite 15  
Enfield, CT 06082  
Mon–Fri 7:30am - 4:30pm  
Closed 12:15pm - 1:15pm  
**860-763-0136**

**Hartford PSC**  
21 Woodland Street, Suite 210  
Hartford, CT 06105  
Mon–Fri 7:00am - 4:00pm  
Closed 12:15pm - 1:15pm  
**860-247-0085**

**Meriden PSC**  
The Beeches  
816 Broad Street  
Bldg 3, Suite 10  
Meriden, CT 06450  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
**203-379--0112**

**Norwich PSC**  
79 Wawecus Street  
Norwich, CT 06360  
Mon–Fri 8:00am - 5:00pm  
Closed 12:15pm - 1:15pm  
**860-823-1817**

**Plainville PSC**  
7 North Washington Street  
Suite 107  
Plainville, CT 06062  
Mon–Fri 7:00am - 5:30pm  
**860-410-1892**

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## New Hampshire Locations

**Exeter PSC**  
19 Hampton Road, Unit 10-B  
Exeter, New Hampshire 03833  
Mon–Fri 7:00am - 4:00pm  
Closed 12:15pm - 1:15pm  
**603-775-0165**

# UMass Memorial Laboratories Patient Service Center Locations

## Rhode Island Locations

### Cumberland PSC

106 Nate Whipple Highway  
Suite 103  
Cumberland, RI 02864  
Mon–Fri 7:00am - 3:30pm  
Closed 12:00pm - 12:30pm  
**401-658-1594**

### Cranston Atwood Ave PSC

673 Atwood Avenue  
Cranston, RI 02864  
Mon–Fri 7:30am–4:00pm  
Closed 12:30–1:00pm  
**401-942-3238**

### Edgewood Medical PSC

251 Park Avenue  
Cranston, RI 02905  
Mon–Fri 8:30am - 5:00pm  
Closed 12:30–1:00pm  
**401-780-9740**

Opening Soon

### East Greenwich PSC

688 Frenchtown Road  
East Greenwich, RI 02818  
Mon–Fri tbd  
**401-tbd**

### East Providence PSC

2761 Pawtucket Avenue  
East Providence, RI  
Mon, Tues, Thurs & Fri 7:30am - 4:00pm  
Closed 12:30 - 1:00pm  
Wed 7:30am - 12:00pm  
Sat 8:00am - 12:00pm by appt  
**401-431-6060**

### North Providence PSC

1830 Mineral Spring Avenue  
North Providence, RI 02904  
Mon-Fri 8:00am - 8:00pm  
Sat-Sun 8:00am - 4:00pm  
**401-353-7220**

### Pawtucket Beechwood PSC

109 Beechwood Avenue  
Pawtucket, RI 02860  
Mon-Fri 8:30am - 5:00pm  
Closed 12:00pm - 1:00pm  
**401-729-7550**

Opening Soon

### Pawtucket Prospect St PSC

56 Prospect Street  
Pawtucket, RI 02860  
Mon - Fri tbd  
**401-tbd**

### Westerly PSC

27 Crestview Drive  
Westerly, RI 02891  
Mon–Fri 8:00am - 5:00pm  
Closed 1:00pm - 2:00pm  
**401-596-8095**

### Westerly Urgent Care PSC

77 Franklin Street, Suite A  
Westerly, RI 02891  
Mon–Fri 7:00am - 4:00pm  
Closed 12:15pm - 1:15pm  
**401-596-8075**



UMass Memorial  
Medical Center Laboratories  
One Biotech Park, Suite 200  
365 Plantation Street  
Worcester, MA 01605-2376

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## We are one of the largest laboratory providers in New England

UMass Memorial Laboratories has opened a Patient Service Center (phlebotomy draw station) at Stony Creek Medical Center, 6 Business Park Drive, Suite 203, Branford, Connecticut.

## The vision of UMass Memorial Laboratories is:

- To be a leading provider of laboratory services throughout New England, meeting the needs of patients and providers in the region, and
- To be one of the top ten academic medical center-based laboratories in the United States



## **Branford Connecticut PSC**

### **Stony Creek Medical Center**

**6 Business Park Drive, Suite 203, Branford, CT**

Branford/Stony Creek PSC is located at 6 Business Park Dr., Branford, CT.

The hours are Monday through Friday 7:30am-4:00pm.

The phone number at Branford PSC is 203-315-4907.