

# **ATTACHMENT 2**

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## Your Labs in GTR

[Help](#) | [Contact GTR staff](#) | [FAQ](#)

Add a new lab

Migrate data from GeneTests

Sort by: Modified: newest first

### NCBI GTR Laboratory (Incomplete Information, cannot submit)

NCBI GTR Laboratory, National Institutes of Health  
8600 Rockville Pike  
Bethesda, MD 20894

Phone: 555-555-5555  
Fax: 555-555-4444  
Email: [info@gtr.ncbi](mailto:info@gtr.ncbi)

**Lab Director(s)**

John Smith

**Laboratory Affiliations**

National Institutes of Health

**Laboratory Credentials**

None

**Test**

None

Last modified: 3/15/2011

Edit

View Details

### Molecular Pathology Laboratory Network, Inc.

250 East Broadway Avenue  
Maryville, Tennessee, 37804  
United States of America

Phone Number: 1-865-380-9746  
Fax Number: 1-865-380-9191  
Email: [info@mplnet.com](mailto:info@mplnet.com)  
Website: [www.mplnet.com](http://www.mplnet.com)

**Lab Director(s)**

Dr. Nicholas T Potter, PhD, FACMG, Director, Molecular Diagnostics Laboratory

**Laboratory Affiliations**

Geneuity Clinical Research Services ([www.geneuity.com](http://www.geneuity.com))

**Laboratory Credentials**

CLIA Certification, Number 44D0948725, Expiration: 2012-03-07

**Test**

[HCM Cardio Panel](#) for Cardiomyopathy (Incomplete Information)  
[Warfarin Sensitivity Testing](#) for Warfarin sensitivity (Submit this test)

Last modified: 3/14/2011

Submit

Edit

View Details



# Add a New Lab

## Lab Information

## Personnel

## Licensure & Accreditation

## Default Parameters

\*: required input

### Name & Institution

Lab name: \*  Acronyms:

GeneTests ID:

Institution: \*  Acronyms:

Department:

### Address

Country or region:

Street & No:

City: \*

State or province:

Postal code: \*

Make this mailing address public: \*  Yes  No

Phone: \*

Fax:

Email: \*

Website:

### Types of Service

Service:  Order code:

### Affiliation

Name:  Website:

### Participation in programs

Participation in standardization programs: *(Click to select all that apply)*

- ISCA Consortium (International Standards for Cytogenomic Array)
- CETT Program (Collaboration Education and Test Translation)
- Mutation-specific Databases

Participation in data exchange programs: *(Click to select all that apply)*

- ISCA Consortium (International Standards for Cytogenomic Array)
- CETT Program (Collaboration Education and Test Translation)
- Mutation-specific Databases



# Molecular Pathology Laboratory Network, Inc

[Lab Information](#)

**Personnel**

[Licensure & Accreditation](#)

[Default Parameters](#)

## Add a person

First name: \*

Middle Initial:

Last name: \*

Display on GTR site: \*  Yes  No

Primary lab contact: \*  Yes  No

Lab director: \*  Yes  No

Job title:

- Lab Director
- Genetic Counselor
- Nurse
- Research Nurse

Academic degree(s): *(Click to select all that apply)*

- MD
- PhD
- MS
- BS

### Certificates:

[Add new](#)

Medical board:

Medical specialty:

Medical subspecialty:

Credentials: *(Click to select all that apply)*

- FACMG
- CGC

Show credentials after name:  Yes  No

GTR permissions: \*

- View only
- Edit
- Add
- Delete
- All

### Contact information to be displayed on GTR site

Phone:

Email:

Fax:

Supplementary public contact information:

### Contact information for GTR staff use only

Phone:

Email:

Fax:

(The current input will be saved.)

(The current input will not be saved.)

(Finish adding people. The current input will be saved.)



# Molecular Pathology Laboratory Network, Inc

Lab Information

Personnel

Licensure & Accreditation

Default Parameters

John Smith, MD, Lab Director

Delete Edit

### Adding a person

First name: \*

Middle Initial:

Last name: \*

Display on GTR site: \*  Yes  No

Primary lab contact: \*  Yes  No

Lab director: \*  Yes  No

Job title:   
    
 Lab Director   
 Genetic Counselor   
 Nurse   
 Research Nurse

Academic degree(s): (Click to select all that apply)

MD   
 PhD   
 MS   
 BS

### Certificates:

#### Add new

Medical board:

Medical specialty:

Medical subspecialty:

Save

Credentials: (Click to select all that apply)

FACMG   
 CGC

Show credentials after name:  Yes  No

GTR permissions: \*

View only   
 Edit   
 Add   
 Delete   
 All

### Contact information to be displayed on GTR site

Phone:

Email:

Fax:

Supplementary public contact information:

### Contact information for GTR staff use only

Phone:

Email:

Fax:

Add Another (The current input will be saved.)

Cancel (The current input will not be saved.)

Continue (Finish adding people. The current input will be saved.)



[GTR Submission](#)

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## Molecular Pathology Laboratory Network, Inc

[Lab Information](#)

**Personnel**

[Licensure & Accreditation](#)

[Default Parameters](#)

John Smith, MD, Lab Director

[Edit](#) [Delete](#)

Jane Doe, PhD, Genetical Counselor

[Edit](#) [Delete](#)



# Molecular Pathology Laboratory Network, Inc

[Lab Information](#)

[Personnel](#)

[Licensure & Accreditation](#)

[Default Parameters](#)

## CLIA Certification

Certification #:  Exp. Date:

## State License(s)

State:  License #:  Exp. Date:

## Other License(s)

Licensed by:  License #:  Exp. Date:



# Molecular Pathology Laboratory Network, Inc

[Lab Information](#)

[Personnel](#)

[Licensure & Accreditation](#)

[Default Parameters](#)

## Optional: Default Parameters (May be overwritten for specific tests)

Test contact policy:

- Pre-test email/phone consultation
- Post-test email/phone consultation
- Laboratory can accept contact only from health care providers

Specimen source:

Peripheral (whole) blood	▲
Buccal swab	
Saliva	☰
Amniocytes	
Amniotic fluid	
Bone marrow	
Cell culture	
Chorionic villi	
Cord blood	
Cystic hygroma fluid	
Dried blood spot (DBS) card	▼

## Upload Sample Test Reports

Sample negative report:

 

Sample positive report:

 



## NCBI Lab 1: List of Tests

Add a new test

Sort by: Modified: newest first

HCM Cardio Panel **(Incomplete Information)**

**Disease(s):**  
Cardiomyopathy

**Gene(s):**  
HCM

Last modified: 3/21/2011

Edit

View Details



# NCBI Lab 1: Adding a Test

**Basics**   **Ordering**   **Indication**   **Methodology**   **Interpretation**   **Performance Characteristics**

## Test Information

This test is for: \*     Clinical purposes     Research purposes

Laboratory test name: \*   

Short test name:   

Manufacturer's test name:

Other test name:     Name type: **Keyword**   

Purpose of the test: \*    *(Click to select all that apply)*

- Diagnosis
- Screening
- Drug Response
- Risk Assessment
- Presymptomatic
- Mutation Confirmation (family specific or research results, etc)
- Preimplantation genetic diagnosis

Test development: **FDA-reviewed**

Lab unique code:

FDA category designation:

- IVD – In Vitro Device
- RUO – Research Use Only
- IVO – Informational/Investigational Use Only
- LDT – Laboratory Developed Test

## FDA Review

### Add new

FDA review of:

- Test kit(s)
- Assay(s)
- Reagent(s)
- Instrument(s)

FDA regulatory status:

- Reviewed
- Approved
- 510(k) Cleared
- PMA Approved

FDA application #:

Upload FDA approval document:

## Test-Specific License(s)

Licensed by: **NYSCLEP**    License #:     Exp. Date:



# NCBI Lab 1: Adding a Test

- Basics**
- Ordering
- Indication
- Methodology
- Interpretation
- Performance Characteristics

## Ordering Information

URL to order the test:

URL for the test:

Order code:

URL for order code:

Informed consent:  Required  Not required  Based on applicable state law

Pre-test genetic counseling:  Required  Not required

Post-test genetic counseling:  Required  Not required

Test specific lab service:  Test specific lab service code:

Specimen:  Requirement URL:

Who can order this test: *(Click to select all that apply)*

- Health Care Provider
- Public Health Mandate
- Out-of-State Patients
- In-State Patients
- Licensed Physician
- Physician Assistant
- Registered Nurse
- Genetic Counselor

How to order:

Testing strategy:

Citations for testing strategy:

## Contact Information

Contact person:

Contact policy:  Pre-test email/phone consultation  
 Post-test email/phone consultation  
 Laboratory can only accept contact from health care providers



# NCBI Lab 1: Adding a Test

- [Basics](#)
- [Ordering](#)
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## Disease

Name: \*

- Familial hypertrophic cardiomyopathy 10
- Familial hypertrophic cardiomyopathy 4
- Cardiomyopathy, Hypertrophic, Familial

Disease name to be used for display:

Synonyms: *(Click to select all that apply)*

 

- Hereditary ventricular hypertrophy
- Asymmetric septal hypertrophy
- Idiopathic hypertrophic subaortic stenosis

Disease synonym to be used for display:

Preferred acronym:

- 

Acronyms: *(Click to select all that apply)*

 

- 

Disease acronym to be used for display:

Disease type:

- Dysmorphology Syndrome
- Cancer Syndrome
- Neurology

Mode of inheritance:

- 

Disease mechanism:

- 

Similar disorders: *(Click to select all that apply)*

- 

Prevalence:

Citation for Prevalence:

 

Target population:

Citation for target population:

 

# NCBI Lab 1: Adding a Test

- Basics
- Ordering
- Indication
- Methodology
- Interpretation
- Performance Characteristics

**Disease**

Name: \*

Disease name to be used for display:

Synonyms: *(Click to select all that apply)*

Disease synonym to be used for display:

Preferred acronym:

Acronyms: *(Click to select all that apply)*

Disease acronym to be used for display:

Disease type:

Mode of inheritance:

Disease mechanism:

Similar disorders: *(Click to select all that apply)*

Prevalence:

Citation for Prevalence:

Target population:

Citation for target population:



# NCBI Lab 1: Adding a Test

- [Basics](#)
- [Ordering](#)
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- Methodology**
- [Interpretation](#)
- [Performance Characteristics](#)

## Methodology (page 1 of 2)

### Method

Category: \* (Click to select all that apply)

- Method to detect nucleotide changes =5bp
- Method to detect deletions/duplications >5 and <250bp
- Method to detect deletions/duplications =250bp
- Method to detect enzyme/metabolite levels

Primary test methodology:

- PCR-RFLP with Southern hybridization
- RT-PCR with gel analysis
- Trinucleotide repeat by PCR or Southern Blot
- Protein truncation

Platforms: (Click to select all that apply)

- Affymetrix GeneChip
- Agilent microarrays
- CodeLink Bioarray
- NimbleGen microarray

Instruments: (Click to select all that apply)

- Qiagen AutoPure LS
- Qiagen QIAcube
- Tecan Genesis Robotic Workstation 150
- PerkinElmer Victor3 1420 Multilabel Plate Reader
- Agilent 2100 Bioanalyzer
- Applied Biosystems 7900HT Sequence Detection System
- Applied Biosystems SOLiD v4 System Sequencer

Test procedure:

Confirmation of test results:

Test comment:

Save & Continue



# NCBI Lab 1: Adding a Test

[Basics](#) [Ordering](#) [Indication](#) **Methodology** [Interpretation](#) [Performance Characteristics](#)

Methodology (page 2 of 2) [Return to page 1](#)

What the test measure: \*

- Nucleotide Mutations
- Haplotypes
- Chromosome Rearrangements
- Full genome

## Enter Test Targets

Add a new target

Target is identified by:

Gene symbol: \*

Associated Reference Sequences: \* (Click to select all that apply)

- NM\_123456.1
- NM\_123456.3
- NM\_1234577
- Add other reference sequence...

Select relevant exons for each associate reference sequence:

- |             |   |
|-------------|---|
| NM_123456.1 | <input type="checkbox"/> 1-5 (c. 1 - c. 1000) |
| NM_1234577  | <input type="checkbox"/> 1 (c. 1 - c. 100)    |
|             | <input type="checkbox"/> 2 (c. 201 - c. 300)  |
|             | <input type="checkbox"/> 3 (c. 301 - c. 400)  |

Relevant gene variants: (Click to select all that apply)

- All variants
- A123R
- V133T
- Add an additional variant...

Clinical significance of variant A123R:

- Pathogenic
- Presumed pathogenic

Clinical significance applies to condition:

Citations to support the above clinical significance:



# NCBI Lab 1: Adding a Test

- [Basics](#)
- [Ordering](#)
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## Upload Sample Reports

Sample negative report:

Sample positive report:

## Variants of Unknown Significance (VUS): Policy and Interpretation

What is the protocol for interpreting a variation as a VUS?

What software is used to interpret novel variations?

What is the laboratory's policy on reporting novel variations?

Upload sample VUS report:

Are family members with defined clinical status recruited to assess significance of VUS without charge?

- Yes
- No
- Decline to answer

Will the lab re-contact the ordering physician if variant interpretation changes?

- Yes
- No
- Decline to answer

Research performed after clinical testing is complete:





# NCBI Lab 1: Adding a Test

- [Basics](#)
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## Availability

Test performance location(s): \*

- Entire test performed in-house
- Entire test performed externally
- Specimen preparation performed in-house
- Specimen preparation performed externally
- Wet lab work performed in-house
- Wet lab work performed externally
- Interpretation performed in-house
- Interpretation performed externally
- Report generated in-house
- Report generated externally

If parts of the test is performed externally: \*

- I am authorized to enter details of the test:  Yes  No
- This entry has been reviewed by the external collaborator(s) for accuracy:  Yes  No

## Analytical Validity

Analytical validity: \* (Discuss number of specimens, analytical specificity, precision, and accuracy)

Citations to support analytical validity: \*

Add Another

## Assay Limitations

Assay limitations: (Discuss limit of detection and test restrictions)

Citations to support assay limitations:

Add Another

## Quality Control

Is proficiency testing performed for this test?  Yes  No

Method for proficiency testing:

Formal PT program	▲
Alternative assessment	<input type="checkbox"/>
Intra-laboratory	▼

Provider for proficiency testing:

CAP	▲
Alternative assessment	<input type="checkbox"/>
Intra-laboratory	▼

CAP test list:

Item1	▲
Item2	<input type="checkbox"/>
Item3	▼

Description of proficiency testing method: (Discuss testing results, reportable range, testing intervals, and number of specimens per interval)

Citations to support the above statement:

Add Another

Description of Internal test validation method: (Discuss reportable range)

Citations to support the above statement:

Add Another

## Clinical Validity

Statement of clinical validity:

Citations to support the above statement:

Add Another

## Clinical Utility

Statement of clinical utility: (Discuss how the test is useful for the public, utility of outcomes, benefits, added value, and associated treatments)

Citations to support the above statement:

Add Another

Save & Continue

