

ATTACHMENT 2

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Your Labs in GTR

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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

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
Website: 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)

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: * | <input type="text"/> | Acronyms: | <input type="text"/> |
| GeneTests ID: | <input type="text"/> | | |
| Institution: * | <input type="text"/> | Acronyms: | <input type="text"/> |
| Department: | <input type="text"/> | | |

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 Add Another

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
- IUO – 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: Browse

Save

Test-Specific License(s)

Licensed by: License #: Exp. Date:

NYSCLEP Add Another

Save & Continue



NCBI Lab 1: Adding a Test

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

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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

