ATTACHMENT 2

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

Your Labs in GTR

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

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

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:* United States

Street & No:

City:*

State or province:* Alabama

Postal code:*

Make this mailing address public:* Yes No

Phone:*

Fax:

Email:*

Website:

Types of Service

Service: Order code:

Genetic counseling Add Another

Affiliation

Name: Website:

Add Another

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

Save & Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

Molecular Pathology Laboratory Network, Inc

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: American Board of Obstetrics and Gynecology

Medical specialty: Please select a medical board first

Medical subspecialty: Please select a medical board first

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.)

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

Molecular Pathology Laboratory Network, Inc

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: American Board of Obstetrics and Gynecology

Medical specialty: Please select a medical board first

Medical subspecialty: Please select a medical board first

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.)

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

Molecular Pathology Laboratory Network, Inc

John Smith, MD, Lab Director	Edit	Delete
Jane Doe, PhD, Genetical Counselor	Edit	Delete

Continue Add Another

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

Molecular Pathology Laboratory Network, Inc

CLIA Certification

Certification #: Exp. Date: Add Another

State License(s)

State: License #: Exp. Date:

Alabama Add Another

Other License(s)

Licensed by: License #: Exp. Date:

ISO Add Another

Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

Molecular Pathology Laboratory Network, Inc

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: Browse

Sample positive report: Browse

Finish Adding This Lab

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

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

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

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: NYSCLEP License #: Exp. Date: [Add Another]

[Save & Continue]

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

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: Add Another

Specimen: Whole blood Requirement URL: Add Another

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: Add Another

Contact Information

Contact person: John Smith Add New

Contact policy:

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

Save & Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

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)*

Add

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)*

Add

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:

Add Another

Target population:

Citation for target population:

Add Another

Save & Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

Disease

Name: * Cardiomyopathy, Hypertrophic, Familial

Disease name to be used for display:
Hypertrophic cardiomyopathy

Synonyms: *(Click to select all that apply)*
Add
- Hereditary ventricular hypertrophy
- Asymmetric septal hypertrophy
- Idiopathic hypertrophic subaortic stenosis

Disease synonym to be used for display:

Preferred acronym:
HCM

Acronyms: *(Click to select all that apply)*
Add
- FHC
- ASH
- IHSS

Disease acronym to be used for display:
HCM

Disease type:
- Dysmorphology Syndrome
- Cancer Syndrome
- Neurology

Mode of inheritance:
- Autosomal Dominant
- Autosomal Recessive
- X-linked

Disease mechanism:
Production of altered protein with changed function

Similar disorders: *(Click to select all that apply)*
- Dilated Cardiomyopathy (DCM)
- Sudden Cardiac Death (SCD)

Prevalence:

Citation for Prevalence:
PMID: 18403758
Add Another

Target population:

Citation for target population:
Add Another

Save & Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

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

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

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 / Chromosome Location

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
- 1-5 (c.1 - c.1000)
- 1 (c.1 - c.100)
- 2 (c.201 - c.300)
- 3 (c.301 - c.400)

NM_1234577

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:

Add Another

Save this target

Save & Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

Upload Sample Reports

Sample negative report:

Browse

Sample positive report:

Browse

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:

Browse

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:

Save & Continue

OMB control number: (0925-xxxx) Expiration date: (xx-xx-xxxx)

NCBI Lab 1: Adding a Test

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 suport assay limitations:

Add Another

Quality Control

Is proficiency testing performed for this test? (•) Yes ( ) No

Method for proficiency testing:
- Formal PT program
- Alternative assessment
- Intra-laboratory

Provider for proficiency testing:

- CAP
- Alternative assessment
- Intra-laboratory

CAP test list:
- Item1
- Item2
- Item3

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

Citations to suport the above statement:

Add Another

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

Citations to suport the above statement:

Add Another

Clinical Validity

Statement of clinical validity:

Citations to suport 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 suport the above statement:

Add Another

Save & Continue