Information Collection Screenshots

Online submission form for the Genetic Testing Registry (GTR)

This document provides updated screenshots of the online form for the submission of genetic test information to the Genetic Testing Registry (GTR).

01/31/2018

SECURE LOGIN SYSTEM

NIH	U.S. National Library of Medicine	🔪 мсві	National Center for Biotechnology Information

Welcome to the submission site for the NIH Genetic Testing Registry (GTR)!

To log in (or create a new account), please click the link "Sign in to NCBI" on the top right corner of this page. Make sure to always use the same log in account.

Here you will be able to register your laboratory and your clinical and research genetic tests. You can update your information at any time. The information entered here displays publicly at https://www.ncbi.nlm.nih.gou/gtr/

The first time you log in you will see the GTR code of conduct and the AMA CPT code agreement before you reach your submission homepage.

To register your laboratory, click the button "Add a new lab". Once you submit your lab information, GTR staff will review it and contact you for more information.

When approved you will be able to register your clinical and research genetic tests manually by clicking the "Add a new clinical test" or "Add a new research test" or by using one of the two excel files available to register clinical tests in bulk. Please register your tests as represented in your lab's catalog. The more information you provide the more discoverable your test will be by GTR users.

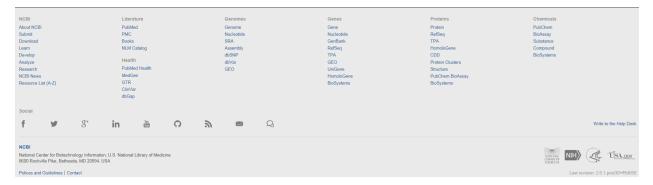
Regardless of how many times you update your data, please submit your annual review once a year as this is a separate action. To submit your annual review, click the "Perform annual review" button to start it and the "Submit" button to finish and submit it.

There is a groups feature where multiple lab staff can work on the same lab and test records, please contact us at <u>gtr@ncbi.nlm.nlh.gov</u> if you would like others in your lab to work on your GTR records.

For more information on how to submit to GTR: <u>https://www.ncbi.nlm.nih.gov/gtr/docs/submit/</u>

Please contact us at gtr@ncbi.nlm.nih.gov if you have questions or if you need any help.

Thank you for participating in GTR!



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Last updated: 2017-11-14T17:07:05Z

GTR CODE OF CONDUCT

GTR Submission

Contact GTR Staff Help Documents GTR Homepage Adriana Malheiro Log out

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Code of Conduct

Test submitters providing test information to the Genetic Testing Registry (GTR) agree to abide by a code of conduct. Failure to honor this code of conduct may result in the removal of the submitter's test information from the GTR. Submitters agree to the following terms in the code of conduct:

- To uphold the integrity of the GTR through the submission of information that is accurate and not misleading.
- To assure the accuracy of the data at the time of submission and to review and, if necessary, update the submitted information at least once a year.
- To make no explicit or implicit claims that the National Institutes of Health, the Department of Health and Human Services, or the U.S. Government approves or endorses tests listed in, or any other information submitted to, the GTR.

To reference their participation in the GTR, test submitters may refer to the fact that information about their tests is available in the GTR and provide the relevant URL(s) but make no explicit or implicit claims that their tests listed in the GTR, or other information submitted to the GTR, have been approved or endorsed by the National Institutes of Health (NIH), the Department of Health and Human Services, or the U.S. Government. If this stipulation is not honored, NIH reserves the right to take action, including, in its sole discretion, removing the submitter's tests from the GTR.

In addition, users are encouraged to report any acts of inappropriate endorsement claims or any other breaches of this Code of Conduct on our Contact GTR page.

I agree Disagree

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Last Revision: 2.6.1.post30+ff5d050

AMA CPT CODE LICENSE AGREEMENT

GTR Submission

AMA CPT Code License Agreement

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Registrants are defined as genetic test developers who are adding their tests to the National Center for Biotechnology Information's Genetic Testing Registry ("Genetic Testing Registry") as maintained by the National Library of Medicine.

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YOUR LABS IN GTR

GTR Submission	Contact GTR Staff Help Documents	GTR Homepage Acting as Lindsey Mighion Switch back to pda malheiro Log out
		OMB NO: 0925-0651 EXPIRATION DATE: 07/31/2018 Burden statement
EGL Genetic Diagnostics	Review lab submission	
Submission Status		Annual Review
Lab ID: 500060		Last review performed: 2018-01-30
Status: processed-ok		Next review due: 2019-01-30
Last modified: 2018-01-17		Perform Annual Review read more
<u>Click here</u> for the public display of this lab. process a submission. If the lab record was the public site may not display your curren	s submitted or edited in the last 48 hours,	Completion resets the next due date one year forward.
If you want to delete this laboratory from	m the GTR, please <u>contact GTR staff</u> .	Lab Director(s)
Lab General Information		Lora Bean, PhD
Lab name: EGL Genetic Diagnostics,	, Eurofins Clinical Diagnostics	Patrida Hall, PhD
Address: 2460 Mountain Industrial Bo	pulevard	John Alexander, PhD
Tucker Georgia 30084		Hussain Askree, MD, PhD
Email: eglcs@egl-eurofins.com		Arunkanth Ankala, PhD
Website: http://www.egl-eurofins.com	n/	
Phone: 470-378-2200 Fax: 470-378-2250		Lab Credentials
Fax: 470-378-2250		QLIA: 11D0683478 exp: 2018-03-15
Submission of Tests		MD - Maryland Department of Health and Mental Hygiene DHMH: 1346 exp: 2018-06-30
		PA - Pennsylvaria Department of Health PADOH: 031676 exp: 2018-08-15
Clinical test: Add a new dinical test		FL - Florida Agency for Health Care Administration AHCA: 800026872 exp: 2019-03-30
Add tests by spreadsh		GA - Georgia Department of Community Health DCH: 044-174 exp: 2018-02-28
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3-Hydroxy-3-Methylglutz Sequencing	aryl CoA Lyase Defi	ciency (HMG): HM	IGCL Full Gene	Clinical test	Processed successfully	<u>Update test</u>	<u>Copy</u>	ID: GTR000502886
3-Hydroxy-3-Methylglutz Deletion/Duplication	aryl CoA Lyase Defi	ciency (HMG): HM	IGCL Gene	Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000502887
3-Methylcrotonyl-CoA Ca Gene Sequending	arboxylase Deficien	cy (3-MCC) : MCCC	1/MCCC2 Full	Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000502913
3-Methylcrotonyl-CoA Ca Deletion/Duplication	arboxylase Deficien	cy (3-MCC): MCCC	C1/MCCC2 Gene	Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000502918
Aarskog-Scott Syndrome	: FGD1 Full Gene S	Sequencing		Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000501493
Aarskog-Scott Syndrome	: FGD1 Gene Dele	tion/Duplication		Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000501833
ACAD9 Deficiency: ACAI	D9 Full Gene Seque	ending		Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000501494
ACAD9 Defidency: ACAI	D9 Gene Deletion/E	Duplication		Clinical test	Processed successfully	<u>Update test</u>	Сару	ID: GTR000502599

ADD A NEW LAB

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Participation in data exchange programs (select all that apply)				
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ab information					
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Institution	NIH				
Name of department	NCBI				
Address	Bethesda Maryland 20892				
Phone	555-555-1234				
Email	GTRIab@lab.com				
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Adriana Malheiro	Lab staff Display this person's information Is this person the primary lab cor Is this person alab director? Yes Job title: Lab Director Professional certifications: Contact information to be display Email: person@GTRAb.com Contact information for GTR staff Email: person@GTRAb.com	itact? Yes			
Gregor Mendel	Research personnel Academic degree: MD Institution: University of Vienna, Contact information: Email: person@lab.com	Vierna, Austria			
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LIST OF TESTS

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Tests in this lab(8)

Add a new research test

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15q13.2-q13.3 Deletion/Duplication	Clinical test	Processed successfully	Update test	Copy	ID: GTR000520904
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Other: 3712.01 exp: 2017-12-31

ADDING A CLINICAL TEST

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GTR Submission — Generic Genetics	Contact GTR Staff	Help Documents	GTR Homepage	Brand Kattman (Log out)
New Clinical Test Basics Ordering Indicaton Methodology Interpretation Performance characteristics Overview				Submission ID:SUB 180908
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Availability				
* Test performance location(s) Identify where all components of the test are performed. Tests which are performed entirely out-of-house should not be registered. Tin-house should not be registered.	ouse' means within the lab/f work done at an outside fac	adlity covered by the ility, briefly describe	e same CLIA c ertific methodology and lo	ation number. Use text box ocation performed.
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Quality Assurance				
Is proficiency testing performed for this test? 📀				
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Clinical Utility				
How likely the test is to improve patient outcomes significantly. Provide references to recommendations or practice guidelines that have b	een issued by authoritative g	roups. If none availa	able, labs may displa	ay a statement explaining
that sufficient research has not been conducted to demonstrate the utility of the test.				-
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GTR Submission	- Generic Genetics	Contact GTR Staff	Help Documents	GTR. Homepage	Brandi Kattman (Log out)
New Clinical Test					Submission ID:SUB 180908
Basics Ordering Indication Me	thodology Interpretation Performance characteristics Overview				
Preview how your test will display	Submit				
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Basics					
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Name	New Clinical Test				
Test purpose	Diagnosis				
Test-specific licenses	License#:				
Ordering					
Informed consent required	Dedine to answer				
Pre-test generic counseling required	Decline to answer				
Post-test generic counseling required	Dedine to answer				
Test-specific services Test-specific additional					
services Contact person	Brandi Kattman				
Condition/Phenotype: Cyst	ic fibrosis				
Mode of inheritance	Autosomal recessive inheritance				
Disease mechanism	loss of function				
Methodology					
Test method(s)	Molecular Genetics, Sequence analysis of the entire coding region, BI-directional Sanger Sequence Analysis				
Test target(s)					
Target is	germline				
Identified by	gene: CFTR: cystic fibrosis transmembrane conductance regulator (ATP-binding cassette sub-family C, memb	oer 7)			
Reference Sequence(s) Variant(s)		,			
Interpretation					
Are family members recruited to assess	not provided				
significance of VUS					
Will the lab re-contact the ordering physician if	not provided				
variant interpretation changes					
Performance characteristic	s				
Test performance	Entire test: internal				
location(s)					
Analytical validity Proficiency testing is	99% sensitivity and specificity.				
performed for this test?	yes				
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New Basics) Participation Condition Methodology Overview					Submission ID:SUB 180909
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Study related to this test					
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URL for the study 🥹	1				
If the study is approved by a research ethics committee (e.g., IF	B), please provide the protocol number 😧				
What is the study type? C Interventional study (or Clinical Trial) C Observational study C Expanded access C Not applicable					
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Study aims and hypotheses 📀					
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Eligibility criteria 🥥				
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Select conditions/phenotypes included in this test:				
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Spongy degeneration of central nervous system				
Niemann-Pick disease, type A Familial dysautonomia				
Bloom syndrome				
Fanconi anemia, complementation group C				
Ganglioside sizildase deficiency				
✓ Cystic fibrosis □ ⊟Tay-Sachs disease				
Hexosaminidase A deficiency, adult type Juvenile (Subacute) Hexosaminidase A Deficiency				
Torsion dy stonia				
Gaucher's disease, type 1				
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Do you want to add a novel condition not in GTR? Add a novel condition				
Continue to the methodology section				
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New Research Test				Submission ID:SUB 180909
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Disease mechanism				
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Prevalence 🥝				
URL for prevalence				
Citations for prevalence 📀				
Add another citation for prevalence (search PubMed)				
Private comment about the condition/phenotype to GTR staff @				
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New Research Test Basics: Participation Condition Methodology Overview				Submission ID:SUB 180909
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* Method category Sequence analysis of the entire coding region				
* Primary Test Methodology Bi-directional Sanger Sequence Analysis				
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Citations for test procedure or protocol 🥹				
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GTR Submission — Generic Genetics	Contact GTR. Staff	Help Documents	GTR Homepage	Brandi Kattman (Log out)
New Research Test Basics Participation Condition Methodology Overview				Submission ID:SUB 180909
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Target is associated with Cystic fibrosis (Needs to be linked to a test target)				
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