



#### **Division of Genomic Diagnostics** PROBAND EXOME REQUISITION AND CONSENT FOR CHOP PATIENTS

LAST NAME	FIRST NAME
MR#	DOB

PLACE PATIENT LABEL HERE OR COMPLETE ABOVE

DO NOT HANDWRITE PATIENT INFORMATION HERE

SHIP TO: Children's Hospital of Philadelphia, Genomic Diagnostics Laboratory, 3615 Civic Center Blvd., Abramson Research Center, 714J, Philadelphia, PA 19104-4302 - Phone: (267) 426-14					
PROBAND INFORM	ATION		TEST INFORMATION		
Patient Name (Last, First, Middle):  Ordering Facility MRN:		Test Requested:  ☐ CHOP Medical Exome, Proband & Family ☐ CHOP Medical Exome, Proband Only ☐ CHOP Medical Exome Reanalysis, Proband & Family* ☐ CHOP Medical Exome Reanalysis, Proband Only ☐ CHOP Medical Exome from Panel			
Sex: Male Female Unknown C					
Date of Birth (Month/Day/Year): Street Address: City/State: Zip/Country:		NOTE: For any of the tests above, additional family member specimens may be submitted for Sanger sequencing to assist with interpretation. If family member specimens are to be submitted, please indicate this on the next page.			
Phone Number: ()	☐ Black/African-American		ew family members (who did not undergo exome e original order) can only be submitted for cing.		
□ Caucasian	☐ French Canadian ☐ Jewish-Sephardic	General Tes	additional genetic testing ordered on the t Requisition		
Sample Type: ☐ Peripheral Blood in EDTA = ☐ Saliva (Contact lab for kits ☐ Cord Blood in EDTA tube ☐ *DNA >15 µg Specify Tis ☐ Other:	) (Maternal Sample Required) sue of Origin:	Checklist of Items to Include:  Proband specimen Specimen of proband's mother (if applicable) Specimen of proband's father (if applicable) Specimens of other family members to be analyzed (please contact lab to discuss) Test requisition form (all billing and clinical information must be completed) Signed informed consent form Family history and pedigree Proband medical records and photographs			
If interested in sending a specimen other the please call the lab to discuss.  *Nucleic acids (DNA or RNA) must be extracterified laboratory.  Collection Date (Month/Day/Year):  Collection Time:AM/P	cted from a CAP or CLIA				
			OTHER ORDERING PROVIDER /		
ORDERING PROVIDER	ORDERING LABOR	ATORY	GENETIC COUNSELOR		
Name (Last, First, Degree) () Phone () Fax	Name (Last, First, Degree) () Phone () Fax		Name (Last, First, Degree) () Phone () Fax		
Institution	Institution		Email		
Street Address	Street Address				
City State	City State				
Zip Country	Zip Country				
Email	Email				
For Lab Use Only Type of billing: ☐ Institutional ☐ CHOP ☐ Se Comments:					
Received by: Received Date:	Received Time:	Sample:			



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SPECIMEN INFORMATION FOR PARENTS AND OTHER FAMILY MEMBERS (IF APPLICABLE)
Proband's Mother's Full Name:
Proband's Mother's Date of Birth: Proband's Mother's MRN: Month/Day/Year
Considering the proband's phenotype, the mother is: $\Box$ Affected $\Box$ Unaffected $\Box$ Unknown
Mother's specimen: $\Box$ Included with this test requisition form $\Box$ To be sent later $\Box$ Not available
Family Member Test requested to aid in proband exome analysis data interpretation:   Exome analysis
☐ Sanger confirmation only
Proband's Father's Full Name:
Proband's Father's Date of Birth: Proband's Father's MRN: Month/Day/Year
Considering the proband's phenotype, the father is: $\ \square$ Affected $\ \square$ Unaffected $\ \square$ Unknown
Father's specimen: $\square$ Included with this test requisition form $\square$ To be sent later $\square$ Not available
Family Member Test requested to aid in proband exome analysis data interpretation: $\square$ Exome analysis
☐ Sanger confirmation only
Family Member's Full Name: Relationship to Proband:
Family Member's Date of Birth: Family Member's MRN: Month/Day/Year
Considering the proband's phenotype, the family member is: ☐ Affected ☐ Unaffected ☐ Unknown
Family Member's specimen: $\square$ Included with this test requisition form $\square$ To be sent later $\square$ Not available
Family Member Test requested to aid in proband exome analysis data interpretation: $\square$ Exome analysis
☐ Sanger confirmation only
Family Member's Full Name: Relationship to Proband:
Family Member's Date of Birth: Family Member's MRN: Month/Day/Year
Considering the proband's phenotype, the family member is: $\square$ Affected $\square$ Unaffected $\square$ Unknown
Family Member's specimen:   Included with this test requisition form   To be sent later   Not available
Family Member Test requested to aid in proband exome analysis data interpretation:   Exome analysis
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#### PROBAND EXOME ANALYSIS CONSENT FORM

This form was designed to guide the consent process for exome analysis and help you to have a discussion with your healthcare provider. You can decide whether or not you want to have this test. We encourage you to ask questions, including questions about other testing options.

#### What is Exome Analysis?

- **Exome analysis** is a genetic test that examines most of a person's genes all at once. **Genes** tell our body how to grow and develop.
- This test can find differences in genes that may explain a patient's health and/or developmental concerns. These genetic differences may also be called *variants* or *alterations*. The primary patient having testing may also be called the **proband**.
- For more information about exome analysis and genetic testing, visit the website: https://imgc.chop.edu/types-ofgenetic-testing/.

#### **How is Exome Analysis Performed at CHOP?**

- This test requires a biological sample, such as blood, from the patient and from one or more biological (or bloodrelated) family members (if available). The laboratory will obtain and look at the DNA (genetic material) from the sample(s).
- The laboratory will compare the patient's DNA sequence (or pattern) to the sequence usually found in healthy people, as well as to that of other family members (if applicable). There may be thousands of differences between the DNA sequences. Most of these differences are normal variation and do not cause health problems.
- The laboratory will use information about the patient's health and the health of family members to identify whether any of the many DNA differences may be the cause of the patient's reason for testing.
- The laboratory will inform the referring healthcare provider(s) about the findings that are most likely to be related to the patient's reason for testing or clinical indication.

#### Clinical Information and Testing of Family Members

- The laboratory needs to have correct information about the health of the patient and family members in order to interpret the results from exome analysis properly.
- The laboratory will use the reason for testing provided by the healthcare provider(s), as well as additional medical records/history, in order to interpret the results. The laboratory does not review the entirety of the patient's medical record/history.
- The laboratory is more likely to identify the genetic cause of a patient's condition when relevant family members are tested at the same time.

#### Secondary Findings

- The American College of Medical Genetics and Genomics (ACMG) recommends that laboratories performing exome analysis purposefully seek and report findings that cause a specific group of rare conditions, even if those conditions are not the reason for the patient's testing. These results are called secondary findings because they are not related to the patient's current reason for testing.
- The conditions associated with secondary findings may lead to serious health problems, such as an increased risk of cancer or heart rhythm issues, or an increased risk for complications from certain kinds of anesthesia. These conditions may be inherited. Some may cause symptoms in infancy or childhood, while others do not usually cause symptoms until adulthood.
- These conditions can in some instances be improved or avoided when monitored or treated. Therefore, they are considered medically actionable.
- Depending on the age and sex of the patient, some secondary findings may have a specific change in medical management that could be pursued within the patient's near (immediate) future and lead to a clear improvement in health outcomes. These findings are considered immediately medically actionable secondary findings in the patient.



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A full Secondary Findings List detailing the genes and conditions currently included in the secondary findings
analysis for this test is available on the laboratory website at http://www.chop.edu/centers-programs/divisiongenomic-diagnostics/requisition-forms or by contacting the laboratory at 267-426-1447.

#### Options for Secondary Findings:

- Testing for secondary findings is optional, and you will make a selection at the end of this form.
- If you select **Option 1** below, the laboratory will purposefully look for and report ALL secondary findings that
  are likely to cause disease. It is possible that this test will not detect all secondary findings, even if Option 1
  is selected. In addition, this test will not look for all causes of the conditions on the Secondary Findings List.
- If you select **Option 2** below, the laboratory will not purposefully look for or report ANY findings on the Secondary Findings List, even if they are identified by chance, unless the finding is possibly related to the patient's reason for testing.
- If you select **Option 3** below, the laboratory will not purposefully look for findings on the Secondary Findings
  List, but will report findings from the list that are identified by chance and are immediately medically actionable
  in the patient or that are possibly related to the patient's reason for testing.
- If you select Option 2 or 3, unreported secondary findings will only be available in the future if a formal exome reanalysis is requested.

#### Secondary Findings in Family Members:

- If a secondary finding is identified in the patient, the laboratory can also look for the finding in family members who have exome analysis at the same time as the patient.
- Family members select whether or not they want to receive this information on the Family Member Test Requisition and Consent form.

#### Other Findings Unrelated to the Reason for Testing

- In addition to secondary findings, this test may in some rare instances detect other results unrelated to the
  patient's reason for testing. Unlike the secondary findings described above, these other unrelated findings are
  NOT purposefully sought but are found by chance while performing the test. These findings are sometimes called
  incidental findings because they are found incidentally.
- The lab will report *medically actionable incidental findings* that are likely to cause serious health problems and have a well-established change in management or treatment. These include childhood onset conditions or conditions with a recommended change in medical care that could take place within about ten or twenty years.
- We generally only report incidental findings that are medically actionable. There are rare exceptions when we may report findings that are *not* medically actionable. Examples include but are not limited to: 1) if they explain some of the patient's symptoms that are not included in the clinical indication for testing, 2) if they are associated with another finding (such as a large deletion or missing region of genetic material) that is believed to be associated with the patient's clinical indication for testing, or 3) if they are associated with an untreatable, serious, childhood onset disorder that is highly likely to cause symptoms (as reporting these findings could help to avoid additional testing and future delays in diagnosis).

#### What will the Laboratory Find and Report?

- The test result might be diagnostic, inconclusive, or negative.
  - A diagnostic result means that the test identified a genetic variant that is likely to explain the patient's reason for testing.
  - An *inconclusive* result means that the test identified variant(s) in a gene that may explain the patient's reason for testing, but there is not enough information available to be certain. (The laboratory will inform the patient's healthcare provider if a clinically significant change in interpretation is identified in the future.)
  - A negative result means that the test did not identify any genetic variants that could explain the patient's reason for testing. This result does not rule out the possibility that the patient has a genetic disorder that was unable to be detected by the exome test at this time.



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- The report will include:
- DNA variants that were detected that may be the cause of the patient's reason for testing and which family members have this variant (when possible).
- ONA variants that were detected and are *not* related to the patient's reason for testing and which family members have this variant (when possible):
  - 1) Secondary findings, only if Option 1 below is selected.
  - 2) Incidental findings identified by chance that are medically actionable or meet the exception criteria above.
- All findings will be included in the patient's report. Separate reports will not be issued automatically for family members.

#### What are the Limitations of Exome Analysis?

- Exome analysis does not look at all of a person's genes. Many genes will not be examined completely or at all.
- Exome analysis does not find all genetic variants or risk factors for common diseases.
- Exome analysis does not identify all types of DNA variants.
- The results usually do not predict how serious a health condition will be or at what age it will occur.
- The results may or may not improve the patient's treatment or prognosis.
- This test will not always identify the cause of a patient's reason for testing. We expect this test to identify the cause of a patient's reason for testing in about 1 out of every 4 (25%) patients who are tested.
- Exome analysis and our interpretation of the results are based on what is known about genetic diseases at the time the test is performed. As time passes, more information about genetic diseases and genetic testing may become known. Exome tests performed in the future with new knowledge may provide different results. Although the laboratory may perform limited reanalysis of exome data for internal purposes (such as quality improvement), laboratory-initiated reanalysis of the raw exome data is not performed routinely. A healthcare provider may request reanalysis of exome data as a part of future care for an additional fee. A new consent form may not be requested if your provider orders reanalysis.

#### What are the Potential Risks of Exome Analysis?

- This test could suggest an incorrect genetic cause for the patient's symptoms or not identify the true cause of a patient's reason for testing, due to limitations of current scientific knowledge and technology.
- We may learn more about these results in the future. The results you receive from the test may later be interpreted differently as a result of evolving research and knowledge in the field. It is appropriate to follow up with your clinician from time to time regarding possible new information about the test results.
- This test may identify results that have an uncertain meaning (variants of uncertain significance).
- This test may reveal unexpected findings unrelated to the patient's reason for testing.
- Although it is not the intended purpose, this test may identify a difference in biological family relationships that may
  or may not be expected by the family. For example, the results may show that the patient's biological mother or father
  is someone different than originally believed. It may be possible to tell a difference in biological family relationships
  from the results report. In some cases, such as when results suggest the possibility of incest, the hospital may be
  required to report this information to appropriate authorities.
- This test may find results that impact the health or future reproductive decisions of the patient or family members.
- This test may find results that could affect the patient's or family member's ability to buy life insurance, disability insurance, or long-term care insurance in the future.
- Because exome analysis is complex, the cost of this test may be higher than other genetic testing. Exome analysis may or may not be covered by insurance.
- If you are concerned about cost, please discuss your questions with your healthcare provider, insurance company, or the CHOP Family Health Coverage Program (1-267-426-0359) before proceeding with testing.



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#### Results Reporting and Confidentiality

- We will report the results to the healthcare provider(s) or institution who ordered the test.
- We will release results to individuals not associated with CHOP if we have written permission from the patient, the patient's legal representative, or as required by law.
- The results report will become part of the patient's medical record and therefore has the potential for future release.
- The patient's health insurance provider or other parties may have legal access to the test results.
- In rare instances, CHOP may ask external (non-CHOP) clinical laboratories to perform all or part of the exome test. The external laboratory may keep copies of the patient's genetic information, including raw genetic data and/or results reports.
- For more information about how CHOP can use or share your information see the Notice of CHOP Privacy Practices (https://at.chop.edu/general-counsel/compliance-privacy/privacy/Shared%20Documents/hipaa npp.pdf).
- The samples and raw genetic data relating to the patient without identifiers, such as name and date of birth, may be maintained in CHOP-based databases and may be shared with external genetic databases that are not located at, owned by, or operated by CHOP. These databases were created to improve our understanding and interpretation of genetic results and ensure that clinical genetic laboratories are interpreting results in the same way. The information contained in these databases may also be used for research purposes.

#### **Future of the Information and Samples**

#### Storage and Sharing of the Information and Samples

- We will keep raw genetic data for at least two years, as per professional and regulatory guidelines. We may destroy it after that time.
- CHOP is not a DNA storage or banking facility. There is no guarantee that patient samples will be available or usable for additional or future testing.
- We will keep the patient's raw genetic data on a secure server/computer that is in a separate section of the medical record and only accessible by authorized personnel. Future access to this data may or may not be available. If you want access to the raw genetic data, please contact the laboratory. There may be an associated cost.
- The laboratory will only release the raw genetic data with identifiers, such as name or date of birth, with the written permission of the patient, patient's legal representative, or as required by law.
- External clinical laboratories who perform all or part of the exome test may keep copies of the patient's genetic information.
- The samples and raw genetic data relating to the patient without identifiers, such as name and date of birth, may be maintained in CHOP-based databases and may be shared with external genetic databases that are not located at, owned by, or operated by CHOP. These databases were created to improve our understanding and interpretation of genetic results and ensure that clinical genetic laboratories are interpreting results in the same way. The information contained in these databases may also be used for research purposes.

#### Reanalysis

- A healthcare provider may request reanalysis of exome data as a part of future care for an additional fee.
- In addition, although not performed routinely, the laboratory may independently initiate limited reanalysis of a patient's (and any submitted family members') exome data for internal purposes, such as quality improvement. We may share new relevant information from this laboratory-initiated reanalysis with your ordering provider or other appropriate healthcare providers. Please discuss with your healthcare provider about receiving any updated information.



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				TION	

#### **Choice for Secondary Findings**

Please Note: the laboratory cannot proceed with the test until you select an option below

Please initial one of the options below regarding your choice for secondary findings in the patient. (The adult patient or a parent/guardian of a minor child must initial next to the selected option.)

	Secondary Findings Options						
Box Next to Option Second		Lab Looks for Secondary Findings	Lab Reports Secondary Findings	Details			
	Option 1	Yes	Yes	I want the lab to look for and report ALL detected disease causing variants on the Secondary Findings List.  NOTE: It is possible that this test will not detect all secondary findings. In addition, this test will not look for all causes of the conditions on the Secondary Findings List.			
	Option 2 No No		No	I DO NOT want the lab to look for or report <i>any</i> secondary findings. I understand that some of these findings may be <i>immediately medically actionable</i> in the patient. I am aware that I will not have access to these results later.  NOTE: If you choose this option, findings that are possibly related to the patient's reason for testing and also involved a gene/condition on the Secondary Findings List will still be reported.			
	Option 3	No	Yes, if found by chance and immediately medically actionable	I DO NOT want the lab to purposefully look for secondary findings. I want the lab to report secondary findings identified by chance if they are immediately medically actionable in the patient.			

#### **Genetic Counseling and Clinical Interpretation**

- We recommend that you seek genetic counseling before you decide whether or not you want to have this test and when you receive the test results.
- If you would like to see a genetic counselor, please ask your healthcare provider to refer you to one in your area. You can find a genetic counselor near you by visiting www.nsgc.org.
- The healthcare provider who ordered this test will make the final interpretation about what the results mean for the patient and provide follow-up recommendations.

By signing this document, you are agreeing that the test, its limitations, and use and retention of related data and samples have been explained to you and you consent and agree to the test and these uses.

Patient/Parent/Guardian Statement: I acknowledge that I have discussed the benefits, risks, and limitations of exome analysis with my healthcare provider(s). I consent to exome analysis.

Patient Signature	Pi	Printed Name			Time
Parent/Legal Guardian if Different from Patient Signature	Pi	rinted Name		Date	Time
<b>Healthcare Provider's Statement:</b> I have explair analysis to this individual and addressed his/heinterpret the clinical relevance of the results for thi	r questions about th	ne test. I u	understand that it	is my respo	onsibility to
Healthcare Provider Signature	Printed Name	/_ and	Contact Number	Date	Time
Interpreter Signature/Witness Signature (Circle Relevant Role)	Pi	rinted Name		Date	Time

# Our Commitment to Diverse Populations

The Children's Hospital of Philadelphia complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. The Children's Hospital of Philadelphia does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

The Children's Hospital of Philadelphia:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - o Qualified sign language interpreters
  - o Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - o Qualified interpreters
  - o Information written in other languages

If you need these services, contact 1-800-879-2467.

If you believe that Children's Hospital of Philadelphia has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: The Family Relations Office, 3401 Civic Center Blvd, Philadelphia, PA 19104, Phone: 267-426-6983, Fax: 267-426-7412, Email: <a href="mailto:familyrelations@email.chop.edu">familyrelations@email.chop.edu</a>
You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Family Relations is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at

https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD) Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

October 2016



### CHOP is Committed to Language Accessibility

If you speak another language, assistance services, free of charge, are available to you.

Español-Spanish ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-879-2467.

繁體中文-Chinese 注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1-800-879-2467。

ملحوظة: إذا كنت تتحدث اللغة العربية فإن خدمات المساعدة اللغوية تتوفر لك بالمجان- اتصل بالرقم Arabic - العربية .1-800-879-2467

Tiếng Việt-Vietnamese CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Goi số 1-800-879-2467.

Français-French ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-879-2467.

Português-Portuguese ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 1-800-879-2467.

नेपाली-Nepali ध्यान दिनुहोस्: तपाईंले नेपाली बोल्नुहुन्छ भने तपाईंको निम्ति भाषा सहायता सेवाहरू निःशुल्क रूपमा उपलब्ध छ । फोन गर्नुहोस् 1-800-879-2467 ।

**ខ្មែរ-Cambodian** ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1-800-879-2467។

বাংলা-Bengali লক্ষ্য করুনঃ যদি আপনি বাংলা, কথা বলতে পারেন, তাহলে নিঃখরচায় ভাষা সহায়তা পরিষেবা উপলব্ধ আছে। ফোন করুন ১-800-879-2467।

Русский-Russian ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-879-2467.

한국어-Korean 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-879-2467 번으로 전화해 주십시오.

Bahasa Indonesia-Indonesian PERHATIAN: Jika Anda berbicara dalam Bahasa Indonesia, layanan bantuan bahasa akan tersedia secara gratis. Hubungi 1-800-879-2467.

Türkçe-Turkish DİKKAT: Eğer Türkçe konuşuyor iseniz, dil yardımı hizmetlerinden ücretsiz olarak yararlanabilirsiniz. 1-800-879-2467 irtibat numaralarını arayın.

Polski-Polish UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-879-2467.

Italiano-Italian ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 1-800-879-2467.

हिंदी-Hindi ध्यान दें: यदि आप हिंदी बोलते हैं तो आपके लिए म्फ्त में भाषा सहायता सेवाएं उपलब्ध हैं। 1-800-879-2467 पर कॉल करें।

ગુજરાતી-Gujarati સુયના: જો તમે ગુજરાતી બોલતા હો, તો નિ:શુલ્ક ભાષા સહ્યય સેવાઓ તમારા માટે ઉપલબ્ધ છે. ફોન કરો 1-800-879-2467.

Tagalog-Tagalog-Filipino PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-800-879-2467.

日本語 - Japanese 注意事項:日本語を話される場合、無料の言語支援をご利用いただけます。1-800-879-2467 まで、お電話にてご連絡ください。

**Deutsch-German** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-879-2467.

Deitsch-Pennsylvania Dutch Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebber gricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: 1-800-879-2467.