UncoverT1D Early Detection Program Requisition

This test requisition form is for submitting specimens to the Uncover T1D Early Detection Program sponsored by Sanofi. Please ensure all fields and check boxes are completed clearly and accurately.

UncoverT1D Early Detection Program is for screening purposes only.

STEP 1: PATIENT INFORMATION

Patient's First Name | Middle Initial | Patient's Last Name

MM/ DD /YYYY
Patient's Date of Birth

Assigned sex at birth: ○ Male ○ Female ○ Unknown

Patient's Street Address | City / Town

Province | Postal Code | Country | Patient's Preferred Phone | Patient's Email

Ethnicity (check all that apply): ○ Indigenous ○ White (European origins) ○ Black ○ East Asian/South East Asian
○ Middle Eastern ○ South Asian ○ South American /Central American ○ Caribbean ○ Other (specify)_____

ELIGIBILITY FOR TESTING (MORE THAN ONE SELECTION MAY APPLY)

Eligibility for testing includes: ○ First degree relative with T1D (parent, sibling, child) ○ Second degree relative with T1D (cousin, aunt, uncle, niece, nephew, grandparent)
○ Family history of autoimmune disease ○ Personal history of autoimmune disease ○ Potentially misdiagnosed pre-diabetes or type 2 diabetes
○ Other _____

PATIENT SPECIMEN INFORMATION

SPECIMEN TYPE: ○ Dried Blood Spots (DBS) Collection Date: MM/DD/YY

Specimen collection services requested? ○ Yes ○ No If yes, see Service Phlebotomy Specimen Collection Request section.

SERVICE PHLEBOTOMY SPECIMEN COLLECTION REQUEST:

Patient will be using a service center: ○ Yes ○ No

Patient requires mobile phlebotomy (at home collection): ○ Yes ○ No

KIT TYPE REQUESTED (for service phlebotomy): ○ DBS Pack

Patient Name | Requested Date | Patient Primary Phone Number | Patient Secondary Phone Number

Special Instructions

! To request phlebotomy services, fill the above and email to genomics@revvity.com or fax completed forms to 470-201-1321, or submit online by visiting https://www.revvity.com/category/uncover-t1d and clicking "Request a Kit." (A dried blood spot (DBS) kit will be mailed to your patient ahead of their phlebotomy appointment.)

STEP 2: ORDERING PROVIDER AND REPORTING PREFERENCES

Provider's First and Last Name

Clinic/Hospital/Institution Name | Provider's Email

Provider's Street Address | City / Town | Province | Postal Code | Country

Provider's Phone | Provider's Fax | Provider's Medical License Number

How would you like to receive the report?:
○ Fax ○ Email ○ Portal

PROVIDER SPECIALTY

○ Endocrinologist - Adult ○ Endocrinologist - Pediatric ○ Primary Care Physician ○ Pediatrician ○ Nurse Practitioner ○ Internal Medicine
○ Pharmacist (where applicable) ○ Other (specify)_____

ADDITIONAL PROVIDER AND REPORTING PREFERENCES (IF APPLICABLE)

Name | Email Address

Phone Number | Fax Number

How would you like to receive the report?:
○ Fax ○ Email ○ Portal

For general questions on the collection and return of specimens, please call: Revvity Omics at +1(866)354-2910 or by emailing genomics@revvity.com

FOR INTERNAL USE ONLY				
Date Rec'd_____ Rec'd _____				
TEMP	SPEC	COL	#TUBES	VOL
R/C/F				
R/C/F				
R/C/F				

STEP 3: TEST MENU

Review Specimen Requirements prior to Submitting Specimen.

Participation in the UncoverT1D Early Detection Program requires that patients meet Sanofi's program eligibility requirements. Each participating patient must have a valid Health Care/Interim Health Program card, and reside in Canada (has a main residence in Canada or is currently located in Canada on a Visa or similar). Each patient must further satisfy the Test Eligibility criteria for the particular test(s) ordered by their Provider, as set forth below. It is the Ordering Provider's responsibility to confirm patient Program and Test eligibility.

	TEST REQUESTED - Select One	SCREENING ELIGIBILITY	SPECIMEN TYPE	SPECIMEN COLLECTION OPTIONS†
	FIRST TIME SCREEN: Early Stage Type 1 Diabetes Initial Screen with reflex to individual autoantibody for identification			
☐	T1D001 + T1D002 (Multiplex with IA2A, GADA-65, ZnT8A*) + (IAA**) > with reflex to T1D003 (GAD-65), T1D004 (IA2), and T1D005 (ZnT8A)	• Meets eligibility criteria as indicated above. • Has requested comprehensive 4-autoantibody screening. • Is not otherwise available through public coverage.	Dried Blood Spot	Clinician collection *or* Service Phlebotomy
	CONFIRMATORY: Early Stage Type 1 Diabetes Confirmatory Test with reflex to individual autoantibody for identification			
☐	T1D001 + T1D002 (Multiplex with IA2A, GADA-65, ZnT8A*) + (IAA**) > with reflex to T1D003 (GAD-65), T1D004 (IA2), and T1D005 (ZnT8A)	Confirm the result of one or more positive auto-antibodies.	Dried Blood Spot	Clinician collection *or* Service Phlebotomy
	FOLLOW-UP TESTING: Early Stage Type 1 Diabetes Follow-Up Screen with reflex to individual autoantibody for identification			
☐	T1D001 + T1D002 (Multiplex with IA2A, GADA-65, ZnT8A*) + (IAA**) > with reflex to T1D003 (GAD-65), T1D004 (IA2), and T1D005 (ZnT8A)	To monitor the status of autoantibodies associated with developing T1D.	Dried Blood Spot	Clinician collection *or* Service Phlebotomy

* Insulinoma antigen-2 autoantibody; Glutamic Acid Decarboxylase 65; Zinc Transporter Type 8 autoantibody
** Insulin autoantibody

†To order a kit for clinician collection or service center collection, visit https://www.revvity.com/category/uncover-t1d
To arrange for service phlebotomy, complete all sections on Page 1 and submit online or via fax to 470-201-1321.
Review Specimen Requirements prior to submitting specimen. If appropriate testing option is not listed, please call 1-866-354-2910 to discuss.

SPECIMEN TYPES	CODE	REQUIREMENTS
DRIED BLOOD SPOTS	**DBS**	***Collection Container(s):*** Dried blood spot card ***Collection and Processing Instructions:*** Follow kit instructions. Briefly, allow blood to saturate card until indicated areas are filled and blood has soaked through card. Air dry card at ambient temperature for at least 3 hours. ***Preferred Specimen Condition:*** Follow kit instructions. Store at ambient temperature. ***Shipping Instructions:*** Follow kit instructions. Double bag and ship overnight at ambient temperature.

Ship specimen, test requisition form, and informed consent form by preferred shipping method to Revvity Omics at: Revvity Omics, 250 Industry Dr. Suite 400, Pittsburgh, PA 15275

For general questions on the collection and return of specimen results, please call: Revvity Omics at +1 (866) 354-2910 (Monday-Friday, 8:00AM - 8:00PM EST) or by emailing genomics@revvity.com

STEP 4: BILLING INFORMATION (for internal use only)

☒ **INSTITUTIONAL BILLING**

Sanofi	B0616
Institution/Organization Name	Provider #

STEP 5: PHYSICIAN CONFIRMATION OF INFORMED CONSENT

The undersigned person (or representative thereof) attests that he/she is a medical professional practicing in Canada, in possession of all valid and active licenses required by applicable Canadian federal, provincial and/or territory laws and regulations, and is authorized to order the testing ordered in this UncoverT1D Early Detection Program Requisition form. The undersigned further attests that the patient: (a) meets all applicable UncoverT1D Early Detection Program and testing eligibility requirements; (b) has given appropriate informed consent for the testing ordered, including a discussion of the benefits and limitations, and (c) has been provided with a copy of the Informed Consent Form.The undersigned confirms that the testing is clinically appropriate for the patient, he/she will ensure that the results of testing will be communicated to the patient, and he/she will remain responsible for any medical management required for the patient in connection with the test results. The undersigned further certifies that all information on this UncoverT1D Early Detection Program Requisition form is true to the best of his/her knowledge.

By adding his/her signature, the undersigned hereby confirms the order for screeing services, as well as his/her attestation and informed consent per above.

In addition, the undersigned hereby certifies that the comprehensive 4-autoantibody screening described in this UncoverT1D Early Detection Program Requisition form is not otherwise available through public coverage for the patient.

Signature_____ Date_____

The UncoverT1D Early Detection Program is not intended to and should not interfere in any way with a healthcare professional's or patient's independent judgment and freedom of choice. Healthcare professionals and patients should always consider the full range of testing and treatment options and select those most appropriate for the individual patient.

This informed consent form is for participating in testing for early detection of autoimmune type 1 diabetes (aT1D).

Revvity Omics, Inc., ("Revvity Omics") requires a completed Patient's Informed Consent Form (ICF) for testing to be performed. The ICF must be completed by the patient, or a legally authorized representative of the patient (or by the healthcare provider where permitted under applicable law or regulation). For any patient below the age of majority, the ICF must be completed by the patient's legally authorized representative.

Revvity Omics will report Test results only to your HCP, or as otherwise set forth in the Confidentiality and Privacy Section of this ICF. The purpose of this ICF is to provide you with a description of the Test (defined below) ordered, known risks and benefits of the Test, and information about handling of your personal data ("PD") such as your name, address, date of birth and gender, anonymization and de-identification of personal health information, sample and data retention, research opportunities, and the reporting of secondary findings, if applicable. There is no cost to you for the Test(s) in the UncoverT1D Early Detection Program; the Test(s) are paid for by the sponsor of this program, Sanofi-Aventis Canada, Inc. (Sanofi). Your PD and Test result data may be anonymized and shared with Sanofi for program evaluation, educational planning purposes, and/or scientific study. Anonymized data are data from which personal identifiers have been removed. Your PD, with identifying information, will not be shared with Sanofi. If you receive a diagnosis after using this testing program, you are in no way obligated to be treated with a medication manufactured or sold by Sanofi or its affiliates.

TEST INFORMATION

Your healthcare provider ("HCP") has recommended that you, or your child, receive certain immunological testing (the "Test") as indicated on the submitted Test Requisition Form ("Requisition"). For more information on the reasons your HCP has ordered the Test, and the condition your HCP is having you tested for, please consult with your HCP. You are free to decide if you want this Test performed or not. Providing a Sample (defined below) and undergoing the Test is voluntary and you may withdraw your consent without penalty at any time.

TEST METHOD

If you consent to the Test, a Sample of your and/or your child's blood (Samples) will be taken to facilitate the Test. Your Sample and associated PD will be sent to Revvity Omics' laboratories in the United States for the Test; the majority of testing will be performed at our laboratory headquarters in Pittsburgh, PA. Laws in the United States may not provide the same level of protection for PD as the laws in your home country.

Under some circumstances, including inadequate or poor quality Sample, an additional Sample may be required for Tests to be performed.

TEST RESULTS

Your treating HCP has sole responsibility for all decisions relating to your results, including any diagnosis and/or medical management thereof; Revvity Omics will not provide a diagnosis. Revvity Omics will report Test results only to your HCP, or as otherwise set forth in the Confidentiality and Privacy Section of this ICF, via secure email, a secure internet portal, or fax. Your HCP is responsible for communicating with you regarding the results of the Test and may refer you or your child to a specialist for further clinical evaluation, if applicable.

TEST LIMITATIONS

Negative results do not rule out the diagnosis or risk of type 1 diabetes in the future. A definitive clinical diagnosis should not rely on the results of a single test. Instead, it should be made by the physician after considering all clinical and laboratory findings in the context of the patient's overall clinical picture. Additionally, every therapeutic decision should be made on an individual basis.

TEST RISKS

Taking a blood Sample from you and/or your child may lead to mild pain, bruising, swelling, redness, and a slight risk of infection. Light-headedness, fainting or nausea may occur if your HCP collects blood. or tissue samples. These side-effects are typically brief and transient, but you should contact your HCP if you and/or your child require treatment. Under some circumstances an additional Sample may be required for Tests to be performed.

It is your responsibility to consider the possible impacts, if any, whether direct or indirect, of your Test results on health insurance and/or life insurance/assurance, coverage. Please check local laws for more information.

TEST REPORT

The report will give positive and/or negative results for each of the four auto-antibodies tested for Type 1 Diabetes. Your/your child's medical history and family history can be an integral part of interpreting test results. Please ensure your HCP has filled out your family history correctly on the Requisition.

UncoverT1D Early Detection Program
INFORMED CONSENT FORM

CONFIDENTIALITY & PRIVACY

You have the right to confidential treatment of the Sample and your, or your child's, PD. Your HCP will provide Revvity Omics with PD including your name, date of birth, gender and family history or other diagnosis to help track your Sample and report results. To maintain confidentiality, the Test results will only be released to the referring HCP, to the ordering laboratory, to the patient/guardian, to other HCPs involved in your diagnosis and treatment, as otherwise required by applicable law or regulation, or as otherwise instructed by your HCP in the Requisition. Unless required by law, Revvity Omics will not otherwise disclose your PD to any person or entity except with your written consent. Please note that your Sample and PD will be stored, viewed, processed securely, and protected in compliance with privacy and confidentiality laws/policies.

You and your HCP can control how your Sample and PD are processed. You have the right to request access to your PD, request corrections of any errors in recorded PD, or where PD may be missing or incomplete, ask that it be completed. You also have the right to ask that your PD be erased, subject to applicable law or regulation. You can contact your HCP for such requests and your HCP will contact Revvity Omics, or you can contact Revvity Omics directly via email at: genomics@revvity.com or toll-free by telephone at +1-866-354-2910. If requests for access, correction, completion, or erasure cannot be fulfilled, you will be informed and provided with the reasons why your requests cannot be fulfilled.

SAMPLE AND DATA RETENTION

Pursuant to laboratory best practices, the Sample will be retained by Revvity Omics for a minimum of 60 days and then destroyed. Additionally, your PD, the data from the Tests (including those performed before any withdrawal of consent) and the related reports will be retained by Revvity Omics for a minimum of two years and then destroyed. In some instances, it may be beneficial to you for Revvity Omics to retain your Sample for a longer period of time in order to conduct additional testing, and Revvity Omics will do so with appropriate documentation from you or your HCP.

Revvity Omics is requesting consent to keep you and/or your child's anonymized Sample and data indefinitely. This consent is optional, and the Test will be performed whether or not you provide consent to the following:

- Revvity Omics will anonymize and retain your Sample indefinitely for internal quality control, test validation, assay development and improvement. By allowing Revvity Omics to retain your Sample, you understand and agree that you give up any property rights you may have in the Sample and are donating it to Revvity Omics. If you withdraw your consent to use of your anonymized Sample, no further anonymization will be performed.

  ❑ Check here if you would like to opt in to anonymized Sample retention.

- Revvity Omics will anonymize your data and retain the anonymized data and related anonymized reports from your Tests indefinitely for statistical and quality analysis, research, scientific and technical development, and market research. Revvity Omics may also share your anonymized data and anonymized report with third parties.

  ❑ Check here if you would like to opt in to anonymized data retention.

RESEARCH OPTIONS

Revvity Omics may collaborate with scientists, researchers and drug developers to advance knowledge of some orders. If there are opportunities to participate in future research relevant to the disease in you and/or your child, Revvity Omics may contact you or your HCP about the development of new testing, drug development, or other treatments.

❑ Check here if you would like to opt in to contact regarding future relevant research studies.

WITHDRAWAL OF CONSENT

I understand this consent is voluntary and is valid until I withdraw my consent. I understand I may withdraw my consent to Sample and data retention, and to the Test at any time, that Revvity Omics will not perform the Test unless I provide consent to the Test. If I withdraw any consent, it will not affect actions taken before I withdrew my consent, including any anonymization of data or of my Sample. I understand that if I wish to withdraw my consent I should contact Revvity Omics via email at: genomics@revvity.com or toll-free by telephone +1-866-354-2910 to request withdrawal.

CONSENT TO TESTING

❑ By checking this box I attest:

I have read and understood the Informed Consent Form in its entirety, including the explanation of why my Sample is being tested, how testing is performed and the risks associated with testing. I have had the opportunity to ask my HCP questions about the information contained herein, and understand that I am entitled to a copy of this ICF. My signature below acknowledges my free consent to the Test, and to the additional consents indicated above, and my understanding and agreement that such testing, including any results or implications thereof, in no way guarantees my health, the health of an unborn child, or the health of other family members.

Patient Signature (or Parent/Guardian if patient is minor)	Date
Patient Name	Name and Relationship (Parent/Guardian if patient is a minor)