

Measuring *C-peptide* to assess beta-cell function is an option for the evaluation of T1D risk

C-peptide is accepted by the American Diabetes Association (ADA) as a measurement of beta-cell function.¹

Produced in a 1:1 ratio with insulin,

C-peptide is a stable, accepted biomarker of beta-cell function²⁻⁵

✓ A relatively constant rate of clearance

✓ Accuracy not affected by exogenous insulin

✓ Half-life of 20 to 30 minutes

C-peptide testing can help provide insight for patients with T1D

	Why does it matter?	How measuring C-peptide can help:
<i>Diagnosis and staging</i>	T1D progresses across 4 stages of increasing beta-cell destruction, ultimately leading to hyperglycemia ^{6,7}	Measuring C-peptide along with islet AAbs (GADA, IA-2A, IAA, ZnT8A) can help distinguish between T1D and T2D ⁸
<i>Risk for progression</i>	C-peptide levels rapidly decline starting 6 months before Stage 3 T1D diagnosis and continuing through 12 months after ⁷	Assess T1D disease progression ⁹
<i>Risk for complications</i>	Low residual beta-cell function is associated with fewer complications (DKA, hypoglycemia, etc) ³	Identify patients at highest risk for T1D complications, particularly those with C-peptide levels <0.6 ng/mL ³

Interpreting results¹⁰

C-peptide provides a quantitative and accepted measure of beta-cell function

C-Peptide Level²

≥0.6 ng/mL* (0.2 pmol/mL)



Interpretation²

Clinically meaningful beta-cell function

Even some residual beta-cell function decreased incidence of microvascular complications in patients with T1D¹¹

*Based on a conversion from 0.2 pmol/mL using the molecular weight of 3020.3 g/mol for C-peptide.¹²

AAb = autoantibody; DKA = diabetic ketoacidosis; GADA = glutamic acid decarboxylase 65 autoantibody; IAA = insulin autoantibody; IA-2A = insulinoma-associated antigen 2 autoantibody; T1D = type 1 diabetes; T2D = type 2 diabetes; ZnT8a = zinc transporter 8 autoantibody.

sanofi

Measure C-peptide to assess existing beta-cell function

While the 2-hour MMTT is used for measuring peak stimulated C-peptide, other methods are available

	<i>Standard (2-hour) MMTT</i> ^{2,13,14}	<i>90-min MMTT</i> ^{2,13,14}	<i>Timed post-meal draw</i> ^{2,5,13-16}
Description	Serial C-peptide serum sampling over 2-hour period following mixed-meal stimulation	C-peptide serum sampling 90 minutes following mixed-meal stimulation	Timed sample within 5 hours of eating
Advantages	Sensitive, specific, and reproducible	Practical surrogate highly correlated to standard MMTT	Practical alternative highly correlated to 90-min MMTT
Limitations	- Most time-consuming - Requires 5 blood draws - Liquid mixed meals not widely available	- Time-consuming - Requires 2 blood draws - Liquid mixed meals not widely available	Indeterminate results require confirmatory testing
Requirements	- Overnight fasting - Administration of standardized mixed meal formula (eg, Boost®, Sustacal®, or similar)* - Draw blood samples for glucose and C-peptide at 0, 30, 60, 90, and 120 minutes	- Overnight fasting - Administration of standardized mixed meal formula (eg, Boost®, Sustacal®, or similar)* - Draw blood samples for glucose and C-peptide at 0 and 90 minutes	- Patients should consume carbohydrate-containing meal within 5 hours of testing - Document time of last meal and glucose level at the time of collection - Draw 1 blood sample for glucose and C-peptide

C-peptide testing for Stage 3 T1D

Diagnostic workup for Stage 3 T1D

<i>Overt hyperglycemia</i> ^{15,18}	<i>Presence of ≥1 AAb(s)</i> ^{15,†}	<i>Beta-cell function</i> ^{2,17}
- HbA1c level of ≥6.5% (≥48 mmol/mol) OR - FPG level of ≥126 mg/dL OR 2-hour PG of ≥200 mg/dL (≥11.1 mmol/L) during OGTT	- Glutamic acid decarboxylase 65 (GADA) - Insulinoma-associated antigen 2 (IA-2A) - Insulin (IAA) - Zinc transporter-8 (ZnT8A)	- C-peptide testing - Patients with C-peptide ≥0.6 ng/mL (≥0.2 pmol/mL) have clinically meaningful residual beta-cell function

Considerations for patients who are experiencing DKA

- Consider performing AAb and C-peptide tests to confirm diagnosis of Stage 3 T1D¹⁵
- ADA guidance is to not test C-peptide within 2 weeks of a hyperglycemic emergency¹⁵

*Recommended dosing 6 mL/kg up to 360 mL.

†The ADA recommends testing at risk individuals for GADA, IA-2A, IAA, and ZnT8A AABs.¹⁵

FPG = fasting plasma glucose; HbA1c = hemoglobin A1c; MMTT = mixed-meal tolerance test; OGTT = oral glucose tolerance test; PG = plasma glucose.

Sample codes for diagnostic testing

C-peptide, islet AAb, and glycemic testing can be ordered through major clinical laboratories using the following codes

These codes are examples only; appropriate codes may vary by patient, setting of care, and payer. The provider is solely responsible for determining medical necessity and accurate coding. Sanofi makes no guarantee concerning reimbursement or coverage.

Sample CPT® Codes

CPT code for measuring C-peptide ¹⁹	
Description	Code
C-peptide test	84681
CPT codes for T1D-related pancreatic islet AAb immunoassays ^{19,20}	
Description	Code
Glutamic acid decarboxylase 65 (GADA) autoantibody; Insulinoma-associated antigen 2 autoantibody (IA-2A); Zinc transporter 8 antibody (ZnT8A); Islet cell antibody (ICA)	86341
Insulin antibody (IAA)	86337
CPT code for measuring dysglycemia ¹⁹	
Description	Code
Glucose tolerance test (GTT), 3 specimens (includes glucose)	82951*
Glucose; quantitative, blood (except reagent strip)	82947†
Glucose post-glucose dose (includes glucose)	82950‡
Hemoglobin glycosylated (A1C)	83036

Commercial Lab Order Codes

Quest Diagnostics ²¹	
Description	Code
C-peptide test	372
Diabetes Type 1 autoantibody panel (includes GADA, IA-2A, IAA, and ZnT8A) [§]	13621
Labcorp ²²	
Description	Code
C-peptide test	010108
Diabetes autoimmune profile (includes GADA, IA-2A, IAA, and ZnT8A) [§]	504050

*Measured at 30-, 60-, and 90-minute time points.¹⁵

†Also known as FPG.¹⁵

‡Measured at 2 hours post glucose.¹⁵

§ADA-recommended pancreatic islet AAbs.¹⁵

Most patients have access to low-cost or free C-peptide and AAb testing for the evaluation of T1D

Commercial patients

Pay an average of
\$20 in OOP costs
for both tests^{*,†}

\$8

for C-peptide
testing^{*}

\$12

for T1D AAb
screening[†]

Medicaid-insured patients

More than 90% pay
\$0 in OOP costs
for both tests

92%

for C-peptide
testing^{*}

98%

for T1D AAb
screening[§]

Cost for AAb screening varies by health plan, benefit design, and test. Please check with the patient's health plan to confirm coverage and OOP costs.

^{*}IQVIA. LAAD Medical and Remittance data (Commercial channel) from January 2024 to December 2024 (N=70,000).

[†]IQVIA. LAAD Medical and Remittance data (Commercial channel) from January 2024 to December 2024. Includes commercial claims with one of the following CPT codes: 86341 and/or 86337. Note: The analysis does not differentiate between the number of autoantibodies tested within each claim (N=15,000).

[‡]IQVIA. LAAD Medical and Remittance data (Medicaid channel) from January 2024 to December 2024 (N=16,000).

[§]IQVIA. LAAD Medical and Remittance data (Medicaid channel) from January 2024 to December 2024 (N=4000).

OOP = out of pocket.

References: 1. Palmer JP, et al. *Diabetes*. 2004;53(1):250-264. 2. Leighton E, et al. *Diabetes Ther*. 2017;8:475-487. 3. Maddaloni E, et al. *Diabetes Obes Metab*. 2022;24(10):1912-1926. 4. Stankute I, et al. *Diabetes Res Clin Pract*. 2021;178:108938. 5. Jones AG, et al. *Diabet Med*. 2013;30(7):803-817. 6. Insel RA, et al. *Diabetes Care*. 2015;38(10):1964-1974. 7. Bogun MM, et al. *Diabetes Care*. 2020;43(8):1836-1842. 8. Phillip M, et al. *Diabetes Care*. 2024;47(8):1276-1298. 9. Simmons KM, et al. *Diabetes Technol Ther*. 2023;25(11):790-799. 10. Flatt AJS, et al. *Ann N Y Acad Sci*. 2021;1495(1):40-54. 11. Steffes MW, et al. *Diabetes Care*. 2003;26(3):832-836. 12. National Center for Biotechnology Information. Accessed June 14, 2026. <https://pubchem.ncbi.nlm.nih.gov/compound/C-Peptide>. 13. Hope SV, et al. *Diabet Med*. 2016;33(11):1554-1558. 14. Besser REJ, et al. *Diabetes Care*. 2013;36(2):195-201. 15. American Diabetes Association Professional Practice Committee for Diabetes. *Diabetes Care*. 2026;49(suppl 1):S27-S49. 16. Wagner R, et al. *Diabetes Res Clin Pract*. 2026;231:113047. 17. Sørensen JS, et al. *Diabetes Care*. 2013;36(11):3454-3459. 18. American Diabetes Association. Accessed June 14, 2026. <https://diabetes.org/about-diabetes/diagnosis>. 19. American Medical Association. *CPT® 2025 Professional Edition*. American Medical Association; 2024. 20. Breakthrough T1D (formerly JDRF). Accessed June 14, 2026. <https://www.breakthrought1d.org/early-detection/#:~:text=Insulin>. 21. Quest Diagnostics. Accessed June 14, 2026. <https://testdirectory.questdiagnostics.com>. 22. Labcorp. Accessed June 14, 2026. <https://www.labcorp.com/test-menu/search#testfinder>.