

Measuring *C-peptide* to assess beta-cell function is important for the evaluation and management of T1D

A surrogate endpoint, C-peptide is accepted by the **American Diabetes Association (ADA)** as a measurement of beta-cell function!

Produced in a 1:1 ratio with insulin,

C-peptide is a stable biomarker of beta-cell function²⁻⁴

C-peptide^{2,5}

Reliable measure of beta-cell function

- ✓ 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 and worsening dysglycemia ^{6,7}	Measuring C-peptide along with islet AAbs (GADA, IA-2A, IAA, ZnT8A, ICA) 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 progression toward Stage 3 in patients diagnosed in Stage 1 or 2 ⁹
<i>Risk for complications</i>	Even 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

C-peptide testing can be a helpful tool to diagnose patients with T1D²

C-peptide test can be a useful T1D diagnosis tool for identifying patients with autoimmunity¹⁰

Measure C-peptide to assess existing beta-cell function

C-peptide is optimally measured postprandially (stimulated)²

	Single draw (non-fasting test) ²	Multiple draws (dynamic test) ²
Description	Measures C-peptide level after typical, nonstandardized meal	Measures C-peptide during MMTT or OGTT
What it measures	Real-world insulin secretion	Peak insulin secretion
Required preparation	<ul style="list-style-type: none"> • Patient should eat normally • Draw 1-2 hours after a meal 	<ul style="list-style-type: none"> • Pretest fasting • Glucose challenge • Serial blood draws over a period of several hours
Considerations	Preferred for clinical practice; sufficient for disease-modifying therapies	May be required for some clinical trials

Interpreting results¹⁰⁻¹⁴

C-peptide provides a direct, quantitative, and validated measure of beta-cell function

C-Peptide Level

≥0.6 ng/mL* (0.2 pmol/mL)



Interpretation

Clinically meaningful beta-cell function

≥0.09 ng/mL* (0.03 pmol/mL)



Detectable residual beta-cell activity

C-peptide testing can enhance the diagnostic workup for Stage 3 T1D

Diagnostic workup for Stage 3 T1D

<i>Overt hyperglycemia^{16,17}</i>	<i>Presence of ≥1 AAb(s)^{16,†}</i>	<i>Beta-cell function^{2,13}</i>
<ul style="list-style-type: none"> • HbA1c level of ≥6.5% (≥48 mmol/mol) <p>OR</p> <ul style="list-style-type: none"> • FPG level of ≥126 mg/dL <p>OR</p> <ul style="list-style-type: none"> • 2-hour PG of ≥200 mg/dL (≥11.1 mmol/L) during OGTT 	<ul style="list-style-type: none"> • Glutamic acid decarboxylase 65 (GADA) • Insulinoma-associated antigen 2 (IA-2A) • Insulin (IAA) • Zinc transporter-8 (ZnT8A) • Islet cell (ICA) 	<ul style="list-style-type: none"> • Complete 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

<i>Stabilization¹⁸</i>	<i>Additional testing¹⁶</i>
<ul style="list-style-type: none"> • Post-DKA, patients must first be stabilized with insulin until they achieve a glucose goal of 150 to 200 mg/dL[‡] 	<ul style="list-style-type: none"> • Consider performing AAb and C-peptide tests to confirm diagnosis of Stage 3 T1D • C-peptide testing should be delayed 1-2 weeks post-stabilization to allow recovery of beta-cell function after metabolic stress[†]

*Based on a conversion from 0.2 pmol/mL using the molecular weight of 3020.3 g/mol for C-peptide.¹⁵

†The ADA recommends testing at risk individuals for GADA, IA-2A, IAA, and ZnT8A AAbs.¹⁶

‡ADA guidance is to not test C-peptide within 2 weeks of a hyperglycemic emergency.¹⁷

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
ICA screen with reflex to titer	36741
Labcorp ²²	
Description	Code
C-peptide test	010108
Diabetes autoimmune profile (includes GADA, IA-2A, IAA, and ZnT8A) [§]	504050
Antipancreatic islet cells	160721

*Measured at 30-, 60-, and 90-minute time points.¹⁶

†Also known as FPG.¹⁶

‡Measured at 2 hours post glucose.¹⁶

§ADA-recommended pancreatic islet AAbs.¹⁶

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.

CPT = current procedural technology; 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. Latres E, et al. *Diabetes*. 2024;73(6):823-833. 11. Flatt AJS, et al. *Ann N Y Acad Sci*. 2021;1495(1):40-54. 12. Lachin JM, et al. *Diabetes*. 2014;63(2):739-748. 13. Sørensen JS, et al. *Diabetes Care*. 2013;36(11):3454-3459. 14. Gubitosi-Klug RA, et al. *J Clin Invest*. 2021;131(3):e143011. 15. National Center for Biotechnology Information. Accessed December 10, 2025. <https://pubchem.ncbi.nlm.nih.gov/compound/C-Peptide> 16. American Diabetes Association Professional Practice Committee for Diabetes. *Diabetes Care*. 2026; (48)(suppl 1):S27-S49. 17. American Diabetes Association. Accessed December 10, 2025. <https://diabetes.org/about-diabetes/diagnosis> 18. Alvarez PR, et al. *Cleve Clin J Med*. 2025;92(3):152-158. 19. American Medical Association. CPT® 2025 Professional Edition. American Medical Association; 2024. 20. Breakthrough T1D Formerly JDRF. Accessed December 10, 2025. <https://www.breakthrough1d.org/early-detection/#:~:text=Insulin> 21. Quest Diagnostics. Accessed December 10, 2025. <https://testdirectory.questdiagnostics.com> 22. Labcorp. Accessed December 10, 2025. <https://www.labcorp.com/tests>