

# A High-throughput Mass Spectrometry Assay to Simultaneously Measure Intact Insulin and C-peptide

## Article Publication

### What is already known?

- Fasting levels of insulin and C-peptide can help predict diabetes mellitus.
- Insulin and C-peptide immunoassays lack standardization and results can vary by assay.
- Thus, insulin and C-peptide levels associated with specific degrees of insulin resistance (eg, pre-diabetic, diabetic) have not been distinctly defined. Defining these ranges could be useful for diagnosis.

### What was done in this study?

- The investigators of this study developed and validated a multiplexed liquid chromatography tandem mass spectrometry (LC-MS/MS) assay that simultaneously measures intact insulin and C-peptide in patient sera.
- The LC-MS/MS assay used independently characterized reference materials.
- Validation was done in accordance with Clinical Laboratory Improvement Amendment of 1988 (CLIA '88). Analytical performance specifications that were assessed included analytical measurement range, intra- and inter-day variation, and interference by insulin analogs.

### What were the new findings in this study?

- Analytical measurement range was:
  - 3 to 320  $\mu$ IU/mL (18 to 1,920 pmol/L) for insulin
  - 0.11 to 27.2 ng/mL (36 to 9,006 pmol/L) for C-peptide
- Intra- and inter-day assay variation was less than 11% for both peptides.
- Of the 5 insulin analogues tested, only insulin lispro interfered with accurate measurements of endogenous insulin. Interference was not observed for C-peptide.

### What were the conclusions from the study?

- Investigators developed and validated an automated, high-throughput, multiplexed assay for determination of levels of insulin and C-peptide.
- Assay results are traceable to well-characterized reference materials. Thus, use of this assay could help standardize measurements across studies. It could also help determine clinically important ranges for insulin and C-peptide levels in healthy individuals and in those with specific degrees of insulin resistance.

### Article published in *Clinica Chimica Acta*

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#### Citation

Taylor SW, Clarke NJ, Chen Z, McPhaul MJ. *Clin Chim Acta*. 2016;455:202-208.

#### Webpage

[Scimedirect.com/science/article/pii/S0009898116300183](https://www.sciencedirect.com/science/article/pii/S0009898116300183)