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Method validation can be defined as testing a process or procedure to ensure it works as intended. This validation follows a set of standard steps that are reproducible, ... (AACC) identifies two major steps that are required in the process of method validation.

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Many times, the uncertainty around method evaluations is not due to the validation or verification process, but rather to unfamiliarity with the test method. Staff involved in evaluating a new method should know its features, such as the reporting units, methodology, clinical utility, normal values ranges, important medical decision points, analytical measurement range, and dilution schemes.

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Basic Method Validation addresses healthcare professionals who perform laboratory tests in central laboratories, clinic or outpatient laboratories, and point-of-care settings. This concise, easy-to-read, 320-page manual contains a comprehensive introduction to method validation in the laboratory, from the conceptual idea of method validation to the bench-level specifics of planning an experiment.

Basic Method Validation (June 30, 2003 edition) | Open Library
Validation of clinical LC-MS/MS methods: What you need to know.
Speaker Deborah French, Ph.D., DABCC (CC, TC), FAACC.
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I'm a bit late in calling attention to this, but the latest edition of Contemporary Practice in Clinical Chemistry has a chapter on method validation and verification that I co-authored along with Dr. Dave Koch, the Past President of AACC. For a short one chapter discussion of method validation and verification, this is the current best choice.

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Basic Method Validation by Westgard, June 30, 2003, AACC Press edition, Paperback in English - 2nd edition

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