Accreditation and Quality Assurance for Clinical Liquid Chromatography–Mass Spectrometry Laboratories

Kara L. Lynch, PhD

KEYWORDS

• Liquid chromatography mass spectrometry • Quality management system • Quality control • Quality assurance • Clinical laboratory accreditation • CLSI C62A

KEY POINTS

- The 5 Clinical Laboratory Improvement Amendments' requirements for laboratory accreditation (facility administration, quality systems, proficiency testing, personnel, and inspection) apply to laboratories performing liquid chromatography–tandem mass spectrometry (LC-MS/MS) testing.
- Although there is sufficient guidance on LC-MS/MS method validation and verification, only Clinical and Laboratory Standards Institute C62A provides some guidance on best practices for quality assurance and postimplementation monitoring.
- Quality-assurance monitoring for LC-MS/MS testing should be proactive rather than reactive and should monitor the entire testing process, including preanalytical, analytical, and postanalytical.
- An LC-MS/MS quality-assurance plan should cover overall batch review parameters, individual peak review parameters, system and reagent changes, and assessment of long-term accuracy.

INTRODUCTION

The ability to accurately identify and quantify an analyte with high sensitivity and specificity by the use of selective reactive monitoring has been the driving force for the adoption of liquid chromatography (LS)–mass spectrometry (MS) in the clinical laboratory. The field has seen a significant increase in the number of clinical LC-MS applications in the past decade, and more clinical laboratories continue to adopt the technology for diagnostic testing. Despite its widespread use, there are very few quantitative LC-MS assays approved by the US Food and Drug Administration (FDA); all other assays fall under the

Disclosure Statement: Nothing to disclose.
Department of Laboratory Medicine, Clinical Laboratory, Zuckerberg San Francisco General Hospital, University of California San Francisco, 1001 Potrero Avenue. Building. 5 2M, San Francisco, CA 94110, USA
E-mail address: kara.lynch@ucsf.edu

Clin Lab Med ■ (2018) ■–■
https://doi.org/10.1016/j.cll.2018.05.002 labmed.theclinics.com
0272-2712/18/© 2018 Elsevier Inc. All rights reserved.

FDA classification of laboratory developed test (LDT). An LDT is defined as an in vitro diagnostic test that is designed, manufactured, validated, and used within a single laboratory. Therefore, no 2 LC-MS methods for the same analyte are alike. Despite the variability in the analytical methods used across laboratories, all clinical laboratories are subject to regulations under CLIA and are held to the highest standard of quality. Although there is sufficient guidance on LC-MS method validation and verification, only the Clinical and Laboratory Standards Institute's (CLSI) guidance document C62-A provides some guidance on best practices for quality assurance (QA) and postimplementation method monitoring.[1] QA monitoring for LC–tandem MS (MS/MS) testing should be proactive rather than reactive and should monitor the entire testing process: preanalytical, analytical, and postanalytical. An LC-MS/MS QA plan should cover overall batch review parameters, individual peak review parameters, system and reagent changes, and assessment of long-term accuracy. This article discusses the CLIA's regulations as they apply to LC-MS/MS–based testing and reviews available guidelines for LC-MS/MS QA monitoring.

LIQUID CHROMATOGRAPHY–TANDEM MASS SPECTROMETRY LABORATORY ACCREDITATION

Most clinical laboratories implementing LC-MS testing do so in the context of an existing accredited laboratory. The requirements for accreditation should, thus, be familiar and similar to other laboratory sections. All clinical laboratories in the United States performing diagnostic testing on human specimens operate under direct federal regulation by the Department of Health and Human Services, Center for Medicare and Medicaid Services (CMS). Diagnostic laboratories are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA or CLIA 1988).[2] CLIA definition of a laboratory is "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." CLIA requires clinical laboratories to be either CLIA exempt or hold a CLIA certificate. CLIA-exempt laboratories primarily include research, forensic, federal, and Substance Abuse and Mental Health Services Administration laboratories. Laboratories that preform high-complexity testing, such as LC-MS, require a CLIA certificate of accreditation. The CMS grants private nonprofit accreditation agencies deemed status for accrediting clinical laboratories. The requirements of the accreditation agency must be equal to, or more stringent than, the CLIA's requirements. Common nonprofit accreditation agencies with deemed status that inspect clinical LC-MS laboratories include COLA (formerly Commission on Laboratory Accreditation), the College of American Pathologists (CAP), and The Joint Commission (TJC).

The following sections discuss the CLIA's 5 requirements for clinical laboratory accreditation as they pertain to laboratories preforming LC-MS methods. Where relevant, each section highlights the available guidelines and best practices for routine LC-MS testing. The 5 requirements for laboratory accreditation include facility administration, quality systems, participation in proficiency testing, personnel, and inspection.

FACILITY ADMINISTRATION: CLINICAL LABORATORY IMPROVEMENT AMENDMENTS REQUIREMENT 1

CLIA requires the implementation of written policies and procedures that ensure a safe working environment for the testing preformed. Safety procedures must be accessible

Download English Version:

https://daneshyari.com/en/article/8757269

Download Persian Version:

https://daneshyari.com/article/8757269

Daneshyari.com