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1st Edition

C57

Mass Spectrometry for Androgen and Estrogen Measurements in Serum

This guideline is intended to aid the laboratorian in developing appropriate procedures for the use of mass spectrometry in the measurement of androgens and estrogens.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Mass Spectrometry for Androgen and Estrogen Measurements in Serum

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Abstract

Clinical and Laboratory Standards Institute document C57—*Mass Spectrometry for Androgen and Estrogen Measurements in Serum* is intended to aid the laboratorian in developing appropriate procedures for the use of mass spectrometry (MS) in the measurement of androgens and estrogens. The primary objectives of this document are to provide guidance and establish uniform practices necessary for producing quality data for quantitation of androgens and estrogens. The guideline provides details specific to androgen and estrogen measurement procedures with respect to preexamination (preanalytical) considerations, MS technologies, measurement procedure and run validation, as well as postexamination (postanalytical) considerations.

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Foreword

Androgen and estrogen measurements are widely used in clinical research, public health assessments, and patient care; however, problems that impede the translation of research and clinical findings into viable information for clinicians and scientists have been reported in the performance of these tests. As proposed by the Endocrine Society in a 2007 position statement[1] on measuring testosterone and concluded from the 2008 Centers for Disease Control and Prevention workshop[2] on steroid hormone testing, mass spectrometric procedures can overcome some of the current limitations in testing.

Mass spectrometry (MS) assays need to be developed and properly validated by the laboratory. This new technology, however, is not commonly used in the clinical laboratory and clinical chemists frequently are not familiar with developing these kinds of measurement procedures. As a result, the purpose of this document is to provide accurate, state-of-the-art information and guidance for the appropriate use of MS in the clinical laboratory for selected androgen and estrogen measurements in serum. Thus, this guideline may help in overcoming some of the current limitations in androgen and estrogen testing, and therefore aid in improving patient care and research translation.

Key Words

Androgen, estrogen, mass spectrometry, selected reaction monitoring, steroids

Mass Spectrometry for Androgen and Estrogen Measurements in Serum

1 Scope

This guideline describes principles, requirements, and recommendations of current mass spectrometry (MS) measurement procedures for routine analysis of androgens and estrogens in serum. The main focus of this document is on the analytical validation and clinical application of androgen and estrogen measurement procedures using MS. It includes guidance, references, and QA parameters that will assist with the implementation and operation of MS systems. Information on maintaining appropriate instrument settings and performance parameters, approaches to ensure accurate and precise measurements, measurement procedure validation requirements, QA procedures, and interpretation and reporting of results are included. Recommendations are included for sample preparation, and pre- and postexamination (pre- and postanalytical) considerations.

The intended users of this guideline are laboratorians who perform or plan to perform androgen and/or estrogen tests by MS, MS assay developers, and physicians and researchers involved in androgen and/or estrogen testing.

A general, comprehensive review of MS technologies in the clinical laboratory is provided in CLSI document C50.[3] This guideline is limited to the measurement of total androgens and/or estrogens in serum, referring to the free, bioavailable, albumin-bound androgens and estrogens, and free, bioavailable, sex hormone–binding globulin (SHBG)–bound androgens and estrogens. The focus of this guideline is limited to the measurement of androgens and estrogens commonly used in clinical and research settings that include, but are not limited to: dehydroepiandrosterone (DHEA), dehydroepiandrosterone sulfate (DHEAs), androstenedione, testosterone (T), dihydrotestosterone (DHT), estrone (E1), estrone sulfate (E1s), estradiol (E2), and estriol (E3). This guideline provides information on MS that relates to testing of the above-mentioned steroid hormones. In addition, the purpose of this document is to provide guidance on the appropriate use of MS for androgen and estrogen measurements and cannot cover all the possibilities in this rapidly developing field. The recommendations provided should be interpreted in light of the continuing progression in this discipline.

2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to “standard precautions.” Standard precautions are guidelines that combine the major features of “universal precautions and body substance isolation” practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. The Centers for Disease Control and Prevention address this topic in published guidelines that focus on the daily operations of diagnostic medicine in human and animal medicine while encouraging a culture of safety in the laboratory.[4] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI document M29.[5]