INTRODUCTION

This checklist is used in conjunction with the All Common (COM) and Laboratory General Checklists to inspect a histocompatibility laboratory section or department.

Histocompatibility inspectors must be pathologists, clinical scientists or medical technologists who have extensive experience in the practice of histocompatibility testing, are knowledgeable about current CAP Checklist and CLIA requirements, and have completed CAP Inspector Training. Inspectors should, to the greatest extent possible, be peers of the laboratory being inspected.


Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

APPLICABILITY

The Histocompatibility Checklist covers clinical testing for clinical transplantation support, HLA cellular functional tests, HLA flow cytometry, HLA serology, HLA solid phase assays, and HLA molecular testing.

For histocompatibility testing performed by ***next generation sequencing (NGS) methods,*** *the requirements in the Molecular Pathology Checklist (eg, assay validation, quality control, specimen handling) must be used in conjunction with the Histocompatibility Checklist for inspection.*

DEFINITION OF TERMS

Common, intermediate and well-documented (CIWD) alleles - Common alleles have frequencies of at least 1 in 10,000; intermediate alleles are found at frequencies less than 1 in 10,000 but at least 1 in 100,000; well-documented alleles have been observed five or more times in unrelated individuals but not at the common or intermediate levels.

High resolution typing - A high-resolution typing is defined as an allele or a set of alleles (G or P groups) that encode the same protein sequence for the region of the HLA molecule called the antigen binding site, with the exception of common, intermediate, or well-documented null alleles (CIWD) version 3.0.0, Hurley CL, et al. *HLA.* 2020;95:516-531), which need to be resolved. The high-resolution genotype must include only one unambiguously assigned genotype; however, alternative genotypes can be listed if they do not contain common or intermediate alleles (CIWD) version 3.0.0, Hurley CK, et al. *HLA.* 2020;95:516-531).

Low resolution typing - A low-resolution HLA genotype result provides sufficient information to identify serological splits or their equivalent. In some cases, this may require two-field genotyping results. A list of serological splits can be accessed at: http://hla.alleles.org/nomenclature/index.html.