

The following documents and links to background information are provided for your use in preparing for the upcoming CLIAC meeting.

They are separated by agenda topic area and in the order of when they appear on the agenda.

**CLIA Waived Testing (Day 1, 11/5, morning)**

- Waived testing historical background – Two documents are attached: one lists the major historical milestones with respect to waived testing; and the second describes previous CLIAC recommendations that relate to the criteria and process for waiver and waived testing performance.
- FDA CLIA waiver approval process and criteria – The following link is to the 2008 final waiver guidance for manufacturers issued by FDA:  
<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm079632.htm>

**Virtual Crossmatching for Transplantation (Day 1, 11/5, afternoon)**

- Virtual crossmatching for transplantation – The publication at the following link defines virtual crossmatches and describes the crossmatch process for organ transplantation:  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1440-1797.2010.01414.x/pdf>
- CLIA requirements for histocompatibility testing – the document attached includes a highlighted section of the CLIA histocompatibility requirements that pertain to crossmatching for transplantation. **FDA Draft Guidance on Laboratory Developed Tests (Day 2, 11/6)**
- FDA draft guidance for laboratory developed tests (LDTs) – The following link is to the FDA website for LDTs. This page defines LDTs and provides additional links to FDA's recently published draft LDT and notification guidance's:  
<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/ucm407296.htm>

**Laboratory Biosafety in the United States (Day 2, 11/6)**

- CDC Laboratory Safety Improvement – The following link is to a website designed to keep the public informed of CDC's laboratory safety efforts: <http://www.cdc.gov/about/lab-safety/index.html>
- CDC Ebola Resources - The following link is to the CDC Ebola resource page, which includes a number of additional links and guidance documents - the "For Healthcare Workers" tab includes information for clinical laboratories: <http://www.cdc.gov/vhf/ebola/index.html>