

CLIA Database Usage Checklist

- Search the CLIA database using the test name, manufacturer name, or instrument model
- Verify that your IVD test system or instrument is correctly listed, including manufacturer and catalog number.
- Confirm the official test description and intended use
- Identify the assigned CLIA complexity category (waived, moderate, or high)
- Check whether multiple test methodologies are listed separately
- Download or capture CLIA listing details for internal documentation.
- Use CLIA complexity data to support 510(k) or De Novo submissions
- Align labeling and instructions for use with the CLIA classification
- Validate laboratory eligibility based on complexity requirements
- Document any discrepancies and corrective actions if the database listing differs from internal records.
- Re-check the database periodically (at least annually or prior to regulatory submission) for updates or classification changes