

### 302 Military Hospital of China Medical Ethic Committee

Clinical Study Review Decision

No: 2015-182-D

<b>Clinical Study Topic</b>	Performance verification and comparison of TianLong automatic hypersensitive HBV DNA quantification system with ROCHE CAP/CTM system		
<b>Investigational Product</b>	<b>Chinese</b>		
	<b>English</b>		
<b>IP Category</b>		<b>CFDA Approval No</b>	
<b>Sponsor</b>	302 Military Hospital of China		
<b>CRO</b>			
<b>Clinical Study Profession</b>		<b>Principal Investigator</b>	
<b>Review Document</b>			
<b>Review Determinations</b>			
<b>Approval</b> <input checked="" type="checkbox"/> <b>Contingent Approval</b> <input type="checkbox"/> <b>Disapproval</b> <input type="checkbox"/> <b>Suspension or Termination of Approved Study</b> <input type="checkbox"/>			
<b>Comment</b>			
<p>Two hundred used blood samples for hepatitis B virus (HBV)-DNA testing, HBV-DNA negative samples and high-titer HBV-DNA mixture samples were collected and prepared. These samples were analyzed performance. The performance was determined using the TianLong automatic hypersensitive HBV DNA quantification system (TL system) and the ROCHE COBAS TaqMan HBV assay in combination with COBAS AmpliPrep (CAP/CTM assay).</p>			
<div style="display: flex; justify-content: space-between; align-items: center;"> <div> <b>ECChairman</b> <i>Hui Fen Wang</i> </div> <div> <b>Date</b> 2015.12.28 </div> </div> 			