

## APPENDIX 2: DATA EXTRACTION FORM FOR ACCURACY AND CLINICAL EFFECTIVENESS REVIEW

<b>Reviewer</b>		
<b>Ref ID</b>		
<b>Author, Date</b>		
<b>Country of Origin</b>		
<b>Industry Sponsorship</b>		
<b>Study Design</b>		
<b>Study Duration</b>		
<b>Eligibility Criteria</b>		
<b>Patient Group:</b>	<b>Intervention</b>	<b>Control</b>
<b>Number Enrolled</b>		
<b>Number Completing Study</b>		
<b>Age, Gender</b>		
<b>Other</b>		
<b>Intervention Name:</b>		
<b>Intervention Type</b>	POC INR	Comparator
<b>Accuracy Outcomes</b>		
<p>Agreement between POC INR and comparator test (defined a priori as result difference of a 15% between the POC INR test and the comparator test)</p> <p>Sensitivity and specificity</p> <p>AUC</p> <p>Regression coefficient (correlation)</p> <p>Positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, diagnostic odds ratio, interferences, linearity, carryover (if applicable), correlation between POC and comparator test.</p>		
<b>Clinical Effectiveness Outcomes</b>		
<b>Impact on clinical management</b>		

(e.g., dosing of oral anticoagulants), mean time from blood drawn to INR result report, achieved therapeutic range, time in therapeutic range, thromboembolic event, hemorrhagic event, mortality, bleeding (minor and major), quality of life, non-health benefits, other safety concerns.		
<b>Other</b>		
<b>Notes</b>		

AUC = area under the curve; ID = identification; INR = international normalized ratio; POC = point of care.