REQUEST FOR EXEMPTION OF TEST/METHOD FROM CURRENT LICENSURE FORM (7/20/07)

North Dakota Board of Clinical Laboratory Practice NDCC section 43-48-03.

NOTE: The Board uses three criteria in determining if a test should be exempt:

- (1) Methodology/Instrumentation must be included in *List of Tests Waived by FDA*. If the test is not on this list, it will <u>not</u> be approved for exemption.
- (2) Exemption should improve patient care as well as provide additional staffing options.
- (3) Exemption should have a positive outcome on patient consequences.

Organization Name:						
Address:						
Phone Number:		Fax:		Email:		
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* Please complete a separate form for each test requested. * * You must explain the instrumentation of each test and also must include package inserts. *						
Test Name:						
Methodology:						
Other Known Methods:						
Reason for requesting this						
method be exempt:						
Test Use:						
Currently performed by:						
(title, discipline)						

Please turn over to complete and sign form.

Who do you anticipate performing the method?			
How do you plan to meet the supervision requirements of N.D. Admin. Code 96-02-10-02?			
Quality Control and Calibration requirements:			
Other pertinent information: (such as false positive or false negative rate, sensitivity and specificity data, etc.)			
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Signature of Pe	erson Completing Form	Date	
Return complete NDBCLP PO Box 4103 Bismarck, ND 5			