Software Name: _____

This form documents the evaluation of computer software to determine the necessity for validation studies or software tes
8.8.

For software modifications, the software developer's release notes, if available, should be used to determine if the modifica
minor revision and be retained with this evaluation form.

I. Software Type:
(Select one) _____ New software
      Has it been developmentally validated? _____
_____ New module(s):
      Has it been developmentally validated? _____
_____ Modification (e.g., upgrade)
      Current software version: _____
      Major/Minor revision: _____

II. Software Function:
(select all that apply) _____ This software will be used as a component of instrumentation
(e.g., Genetic analyzer data collection software, Quantitation software, etc.

_____ This software will be used for analysis and/or intepretation of DNA data (e.
This software will be used for statistical calculations
(e.g., STRmix, PopStats, YHRD, AX)
_____ This software does not impact analytical process, interpretation, or statistic
without PopStats)

Internal
Validation:

QAS 8.8.2/ 8.8.3	Functional Testing	Reliability Testing	Precision/ Accuracy	Sensitivity	Specificity
Component of Interpretation	X	X			
DNA analysis/ interpretation	X	X	X (if applicable)	X (if applicable)	X (if applicable)
Statistical Calculations	X	X	X (if applicable)		
Other Software	X				
Minor Revisions	X				

III. Evaluation:

Evaluation will include discussion of which studies are applicable to software type (QAS Stds 8.8.2/8.8.3)

Form Approved By:

Comments:

Technical Leader _____

Evaluated by: _____ Date:

Approved by: _____ Date:

Version: _____

;ting in accordance with QAS

ations resulted in a major or

_____

.)

g., GMID-X, STRmix)

al calculations (e.g., FA, CODIS

Regression Testing (Revisions)
X
X
X

Form Approved By:

Technical Leader _~Mackenzie~ ~J~ ~Dethaan~_