



# Change Information



Document No. :  Effective Date :

Affected Item(s) :  Firmware  Reagent Version  PC Software  Hardware  
 Labeling/Packing/Documents  others :

Change Subject :

Affected Product(s) :

Affected LOT(s) :

Priority :  **Mandatory**  
 Recommended  
 For Information Only

Action(s) Required :  **Immediate action(s) required (URGENT !)**  
 On Failure  
 On next time of on-site service visit  
 Telephone/Email informing Customer(s)  
 No action required

### No.# Change Description

1.	Support new version of assay reagent "AES22" since Aug-19th-2020 manufacturing.
2.	Improve FRU test performance and update Reference Range as : Canine 177~314 umol/L ; Feline 191~349 umol/L
3.	Improve T4 and LIPA test performance.
4.	Improve Na and TRIG test performance with new reagent compound design.
5.	Improve K test performance with improving interference elimination.
6.	Improve assay equation library of CI, BUN, tCO2, ALT, AST.
7.	Improve test performance of certain LOTs for ALB, ALP, CHOL, Na, TP, TBIL and T4.
8.	Improve internal-QC criterion for Error 201, 355 and 3x2 judgement.
9.	Add Polish language of LCD user interface.
10.	Patient-ID and warning sentence will be displayed while Error 202, 204, 213 or 355 occurring.
11.	Interference Index (0, +, ++, +++) normalization : + is about 20%, ++ is about 40%, +++ is more than 50% out of total 29 assays of VB1 test are sample interfered with % symbol displayed.
12.	For service purpose, implement the function of "Assay Parameter Calibration" to calibrate the optical parameters of certain LOTs of assays by reading the barcode of a dummy rotor that provided by skyla service.
13.	For service purpose, implement the function of "Curve Fitting" to calibrate the results to fit with another reference method(machine) for some/all assays by importing a csv file (generate by a PC software or offer by skyla CS) to analyzer.
14.	S/N# of Analyzer will be included in System Version display.
15.	Correct the LCD display of sample type that UPC test should not be the plasma/serum sample.
16.	Change the decimal position of results of UPRO/UCRE(SI) and CREA(Common).
17.	Improve the analyzer system stability.