Stability Testing Report of DUS Series

(Urine Reagent Strips)

Revision History

Revision Records			
Rev.	**Date**	**Description of Changes**	**Approval**
0	2002/10/10	Release to Document Control	director

Signature

Classify	**Prepared by**	**Reviewed by**	**Approved by**
Title	Manager	Director	President
Name	Y.S.Choi	Y.A.Park	J.G..Yun
Sign			
Date	2002/10/10	2002/10/10	2002/10/10

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1. Purpose

This protocol is prepared for the stability testing of DUS Strips. The testing is designed to obtain information that will enable proposals to be made for the shelf life of DUS Strips including the materials and packaging systems used. Each product will have variations depending on the final product format and intending use. To determine the effect of thermal, light and moisture stress which the reagent strips be exposed to during normal and abnormal storage.

2. References

EN 13640: 2002 Stability testing of in vitro diagnostic medical devices.

3. Time schedule

Year	1999		2000						2001				
Month	7	12	2	4	6	8	10	12	2	4	6	8	10
Protocol Approval	★												
Apparatus Equipped	★												
Real-time studies		★			★			★			★		
Accelerated aging studies every 1month	→	→	→										
Review													★
Close													★

4. Description of Device

4.1 Device Name

Common name: Urine Reagent Strip

Trade name: DUS Strips

4.2 Classification

Categorized as “Others” according to AnnexⅨ, IVDD 98/79/EC

4.3 Intended purposes

Diagnosis of disease for reagent strips.

4.4 Product

1) DUS Strips device

A strip of filter paper (Whatmann paper) was immersed in a solution and dried at about 70℃, for about 15minutes. The resultant impregnated dried paper was cut into rectangles measuring 5 by 5 mm. These rectangles were mounted on end of strips of polystyrene measuring about 5 by 112 mm, using double-faced adhesive tape (Double Stick from 3M Co.) to provide urine test device. Test papers of the urobilinogen, glucose, bilirubin, ketones, specific gravity, occult blood, pH, protein, nitrite, leukocytes, and Ascorbic acid are plastic strip attached into the regular square in the 115 × 5mm opposite plastic handle

2) Reagent

Analysis Item	Raw Material	Q'ty (mg)
Urobilinogen	4-Methoxybenzenediazonium tetrafluoroborate.	2.9
Glucose	Glucose oxidase	430U
	Peroxidase	200U
	Potassium Iodide	12.0
Bilirubin	Sodium nitrite	0.733
	2,4-dichloloaniline	2.3
	Sulfosalicylic acid	25

Ketones	Sodium nitroprusside	23
Specific gravity	Bromothymol blue poly (Methyl Vinyl Ether/Maleic acid) anhydride	0.5 140.5
Occult Blood	o-Tolidine Cumene hydroperoxide	35 12
pH	Methyl red Bromothymol blue	0.05 0.5
Protein	Tetrabromophenol blue	0.34
Nitrite	p-Arsanilic acid	4.5
Leukocytes	Induced indole amino acid ester	1.3
Vitamin C	2,6-dichlolo indophenol soduim salt	0.8

4.5 Packaging

The reagent strips are packaged in a HDPE bottle containing a desiccant.

4.6 Storage

Results obtained with DUS strips stored at Room temp. (2-30℃), Moisture(<50%) serve as the reference.

5. Test procedures

5.1 Selection of Samples

Test samples are form normal production. Each 10 Strips from 3 Lot hereinafter.

Item	**DUS Strips**		
Lot. No	US991216	US000608	US001221
Date of Manufacturing	1999.12.16	2000.6.8	2000.12.21

Components	Sub. Lot. No		
Urobilinogen	U991215	U000603	U001215
Glucose	G991210	G000601	G001205
Bilirubin	B991209	B000531	B001210
Ketones	K991208	K000602	K001209
Specific gravity	S991205	S000530	S001207
Occult Blood	O991204	O000604	O001218
PH	H991211	H000529	H001213
Protein	P99212	P000530	P001212
Nitrite	N991207	N000531	N001211
Leukocytes	L991213	L000603	L001218
Ascorbic acid	A991210	A000601	A001211
Quantity	100 strips/bottles	100 strips/bottles	100 strips/bottles
Total Volume	100 bottles	100 bottles	100 bottles

5.2 Apparatus

1) High Temp Oven
- Model: IC-DO45
- Temp Range: Ambient to 120℃
- Temp Controller: Digital P.I.D Controller
- Temp Accuracy: ±1℃ at 150℃
- Dimension (in): 450*450*450(H) mm
- Shelves: SUS 2EA
- Material in: Stainless steel
- Material out: Steel plate epoxy coating
- Safety device: Hydraulic temp controller
- Power: AC220V 2500W

2) Low Temperature & humidity Test Chamber
- Model: DW-TH-1510
- Voltage: 100V or 220V
- Power: 2.100W
- Freezer: 1HP(502)
- Dehumidifier: 1/2HP(12)
- Airing motor: 1/4HP

- Dry control: Digital
- Humidity control: Digital
- Size (in): 600 * 500* 500mm
- Range temp: -30 - +80 ℃
- Range humidity: 25 – 95%
- Humidifier: 1/8HP(3,600)

5.3 Real-time studies

1) Measure and record the lot numbers and initial parameters.
2) Transfer the 10 bottles to the storage chamber with Room Temperature(2 - 30℃), Moisture (<30%)
3) Record the temperature, the humidity and date.
4) Every 1 month tested by the visual comparison with color charts of each concentration range.
5) Control urine value: Standard materials are spiked in negative urine and diluted serially with negative urine.
6) A result is noted ‘Good’ when color and sensitivity of test strip shows 100% all same result with that of Colors Chart.
7) A result is noted ‘Change’ when color and sensitivity of test strip shows 5% over different result with that of Color Chart.

5.4 Accelerated studies

5.4.1 Temperatures selected

1) Measure and record the lot numbers and initial parameters.
2) Place a sufficient amount of 100 strips in the final containers (HDPE bottle) at the select temperatures (40±2°C, 50±2°C, 60±2°C at moisture < 30%)) for each checkpoint.
3) Place 10 extra bottles at each temperature to use in case of discrepancy.
4) Pull bottles at the indicated times (each checkpoints) and allow coming to room Temperature before opening.
5) Compare performance and sensitivity of the reagent strips with the color chart on the label as soon as possible.
6) A result is noted ‘Good’ when color and sensitivity of test strips shows 100% all same result with that of Colors Chart.
7) A result is noted ‘Change’ when color and sensitivity of test strips shows 5% over different result with that of Color Chart.
8) Check Point

Check point	Condition
Daily	60°C
Once every 1 week	50°C
Once every 2 weeks	40°C
Once every 1 month	Room temp.

The tests were stored at the conditions described in the present report from the day of QC release.

5.4.2 Moisture Selected

1) Measure and record the lot numbers and initial parameters

2) DUS 11 test strips were stored in their original packaging at room temperature (comprised between 20°-23°C) for 1 month to 24 months, at the following moisture conditions:

A) < 50%

B) 60-70%

C) > 80%,

DUS Strips were stored in their original container at 2-30°C serve as the reference strips for comparison of results.

3) Place 10 extra bottles at each temperature to use in case of discrepancy

4) Every 6 month tested by the visual comparison with color charts of each concentration range.

5) Compare performance and sensitivity of the reagent strips with the color chart on the label as soon as possible.

6) A result is noted ‘Good’ when color and sensitivity of test strips shows 100% all same result with that of Colors Chart.

7) A result is noted ‘Change’ when color and sensitivity of test strips shows 5% over different result with that of Color Chart.

6. Test Results

6.1 Temperature Stability:

This test consists in observing any change in the physical appearance of the test before use, especially the color change of the pad of each parameter.

DUS Strips stored in their original packaging at 40°C, 50°C, 60°C and room temperature.

Table 6.1.1. Effect of storage at 60°C on the color and sensitivity of DUS Strips pad

Samples	1 week	2 week	3 week	4 weeks							5 weeks	
				1day	2day	3day	4day	5day	6day	7day	1day	2day
US991216	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Change (1%)	Change (3%)
US000608	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Change (1%)	Change (3%)
US001221	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Change (1%)	Change (3%)

Table 6.1.2. Effect of storage at 50°C on the color and sensitivity of DUS Strips pad

Samples	4 weeks	8 weeks	12 weeks	14 weeks	15 weeks	16 weeks
US991216	Good	Good	Good	Good	Good (1% Change)	Change
US000608	Good	Good	Good	Good	Good (1% Change)	Change
US001221	Good	Good	Good	Good	Good (1% Change)	Change

Table 6.1.3. Effect of storage at 40°C on the color and sensitivity of DUS Strips pad

Samples	7 weeks	14 weeks	21 weeks	28 weeks	30 weeks	32 weeks	34 weeks
US991216	Good	Good	Good	Good	Good	Good (1% change)	Change
US000608	Good	Good	Good	Good	Good	Good (1% change)	Change
US001221	Good	Good	Good	Good	Good	Good (1% change)	Change

Table 6.1.4. Effect of storage at room temperature on the color and sensitivity Of DUS strips pad

Samples	1 month	6 months	12 months	18 months	24 months
US991216	Good	Good	Good	Good	Good
US000608	Good	Good	Good	Good	Good
US001221	Good	Good	Good	Good	Good

6.2 Acceptance Temperature

According to the Rule of thumb for stability predictions, our strips will remains for two years at room temperature in all probability if it is still stable in unopened bottle when stored at the following temperatures for the stated period of time.

Temperature(℃)	Time
60	4 weeks
50	14 weeks
40	30 weeks
Room temperature	2 years

The strip in the bottle that is opened and closed frequently will be stabled for two year at room temperature.

6.3 Moisture stability

This test consists in observing any change in the physical appearance of the test before use, especially the color change of the pad of each parameter.

Table 6.3.1 Results obtained with DUS Strips stored at less than 50% moisture:

Samples	1 month	6 months	12 months	18 months	24 months
US991216	Good	Good	Good	Good	Good
US000608	Good	Good	Good	Good	Good
US001221	Good	Good	Good	Good	Good

Table6.3.2 Results obtained with DUS Strips stored at 60-70% moisture:

Samples	1 month	6 months	12 months	18 months	24 months
US991216	Good	Good	Good	Good	Change
US000608	Good	Good	Good	Good	Change
US001221	Good	Good	Good	Good	Change

Table 6.3.3 Results obtained with DUS Strips stored at more than 80% moisture:

Samples	1 month	6 months	12 months	18 months	24 months
US991216	Good	Good	Good	Change	Change
US000608	Good	Good	Good	Change	Change
US001221	Good	Good	Good	Change	Change

6.4 Acceptance Moisture

Moisture (%)	Time
< 50	24 months
60 ~ 70	18 months
> 80	12 months

Moisture stability of DUS Strips is physically stable for 24months when moisture conditions are less than 50% and storage temperature is comprised between 2 -30℃.

7. Approvals

Protocol preparation by: Y. A. Park (Manager QC)

Protocol Approved by: J. G. Yun (President)

8. Testing laboratory

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