

# The EBF DBS Microsampling Consortium: Stability sub team

## Manufacturer and User Surveys



### Background and Aim

- Investigate generic factors affecting stability for DBS
- Provide recommendations for drying times and storage conditions for DBS

### Ongoing Activities and Current Results

- Manufacturer and user surveys prepared and data collated in order to provide recommendations
- It is clear from the manufacturer survey that not all companies have embraced the EBF positioning of DBS within the bioanalytical community
- GE Healthcare (DMPK-A, B and C) recommendations
  - DMPK-A and B cards are affected by temperature & humidity
  - Unused cards should be stored in sealed plastic bags with desiccant (4 x 1 g, per 100 cards). DMPK-B should not be packed directly with desiccant but with a barrier such as a plastic bag
  - DBS samples should be stored as above in individual glassvine envelopes to avoid contamination
  - High humidity environments may affect drying time, therefore drying should be in a controlled environment and stored as detailed above
  - Spots should be dried for 2 hours
- Perkin Elmer recommendations
  - A narrow range of temperature and humidity, do not affect spot size on Ahlstrom 226
  - Store unused cards in their original wrapping, away from direct sunlight and in a manner that avoids compression. It is not clear how they should be stored once opened
  - DBS samples should be stored with desiccant, at low temperatures (4°C, short term; -20°C, long term)
  - Spots should be dried for 3 hours
- Agilent recommendations
  - Spot size is unaffected by temperature and humidity (23 to 80% and 21.5 to 35.5°C)
  - Store unused cards in a zip-loc type bag
  - The cards are non-hygroscopic. Desiccant not required but suggested as a precaution for storage of DBS samples
  - Spots are dry within 2 hours regardless of temperature or humidity
- Conclusions**
  - Store and dry spots as detailed in the earlier text
  - Investigation conditions if using/ storing DMPK and 226 cards at extreme temperature or humidity
  - Until the remaining manufacturers provide data on their cards at high temperatures & humidity it will be necessary to investigate on a case by case basis

### Team Members

- Zoe Cobb, Quotient Bioresearch Ltd
- Neil Spooner, GlaxoSmithKline
- Ludovicus Staelens, UCB Pharma
- Stephen Williams, Charles River Laboratories
- Mira Doig, ABS Laboratories Ltd
- Rebecca Broadhurst, AstraZeneca

Question	Answer	Percentage
Which DBS cards do you use?	DMPK-A	63
	DMPK-B	50
	DMPK-C	50
	Ahlstrom 226	69
	Agilent Bond Elut	13
How do you dry cards after spotting	Ambient temp and humidity	100
	Bagged with desiccant	6
How long do you dry cards for	≤ 1 hour	6
	≤ 2 hour	75
	≤ 4 hour	6
	> 4 hour	13
How do you store your cards	Bagged with desiccant	94
	Bagged without desiccant	13
	Single cards per bag	38
	Multiple cards per bag	31
	Double bagged	19
	1 g desiccant per bag	50
	2 g desiccant per bag	19
	>2 g desiccant per bag	13
Do you change desiccant on sample receipt	Yes	38
	No	31
	Sometimes	31
Do you keep samples in dedicated storage	Yes	94
	No	13
Do you keep samples in the dark	Yes	81
	No	13
What stability do you perform	Ambient	94
	Whole Blood	81
	Freeze/thaw	13
	Humidity	13
	Other / Extremes	31
Do you monitor temperature and humidity during shipping	Temperature	31
	Humidity	19
	Neither	69
Do you monitor temperature and humidity during storage	Temperature	56
	Humidity	19
	Neither	44
Do you have a defined range for temperature and / or humidity	Yes	47
	No	44
Do you validate stability within these ranges	Yes	56
	No	38

- User survey: supports these findings
- 16 companies responded to the survey
  - Majority dry cards for 2 hours
  - Majority store samples in dedicated area and in the dark
  - Majority store individual cards with 1 g desiccant
  - Significant number store multiple cards with >2 g desiccant
  - Inconsistency on stability experiments, monitoring temperature and humidity through storage and shipping

### Future Plans

- Publish recommendations for storage and drying times
- Formulate and publish recommendations for stability experiments and monitoring of temperature and humidity

The data presented herein are derived from investigations at EBF consortium member laboratories in line with pre-defined experimental criteria. It is not the intent of the EBF DBS Microsampling Consortium to endorse any specific product above others. Any limitations observed with certain products are a reflection of the specific experiments conducted for the test materials under investigation.