St. John's Health Sciences Center VIP 5 Tissue Processor: 'Excessive Xylene Fumes'

The following is a detailed description of the troubleshooting events between Somagen Diagnostics and the St. John's Health Sciences Center for the investigation of the possible cross-contamination of reagents as all paraffin reservoirs had an excessive xylene fumes. Somagen Diagnostics was notified of this issue the morning of Monday September 29, 2008. The assessment was completed by Jamie Simpson, Field Service Engineer for Somagen Diagnostics.

Assessment:
On October 1st, 2008 Jamie Simpson was dispatched to do a thorough investigation of two VIP 5 tissue processors (s/n 52151443 and s/n 52151442) because of excessive xylene fumes from paraffin stations 13 and 14. The main contact at this site was Barry Dyer, Divisional Manager of Pathology for Eastern Health. The following is a summary of the information that was provided by Barry Dyer:

- As part of an ongoing inquiry, an inspection team was present at St. John's Health Sciences Center's histology laboratory and inquired about xylene odors in the paraffin reservoirs, reporting that the smell was stronger then it should have been in stations 13 and 14. No measurements in parts per million were taken.

Possible Issues:

- Use of over 100 sponges per day, leading to xylene carryover into the paraffin stations
- Charcoal filter had not been replaced since March 2008
    - Charcoal filters are recommended to be replaced every 20 processing runs as it becomes saturated with xylene molecules.
- Fume control water not being replaced daily
    - Fume control water is part of the fume removal system, and is recommended to be changed every processing run.

Instrument Verification Performed by Jamie Simpson:

a. Pump In/Pump Out verification of pressures
   Rationale: Checks for connections, air leaks, and plugs in the lines. This also checks for pump in / pump out times by the pump, on average 3 minutes in / out (depending on the volumes).
b. Error Log check
   Rationale: To ensure that there were no errors in the log (user cannot delete Error Log only Error List).
c. Reagent placement checked
   Rationale: To ensure fixation, dehydration, and clearing are occurring in the proper order.
d. Program times checked
   Rationale: To ensure the program times conform to laboratory standard operating procedures (SOP).
e. Reviewed maintenance record
   Rationale: To ensure maintenance is up to date and following manufacturer's recommendations.
f. Perform End of Warranty Inspection
   Rationale: To ensure that the machine is in good working condition.
g. Perform routine run over night
   Rationale: To confirm that xylene odors in stations 13 and 14 for VIP 5 tissue processor (s/n 52151443 and s/n 52151442) are acceptable.

Evaluation of Instrument Verification:

a. No errors generated, Pressure and Vacuum are well within appropriate target limits
b. No errors reported in Error Log
c. Reagents in correct placement
    a. Station 1 – 10% Formalin

Station 2 – 10% Formalin
Station 3 – 70% Alcohol
Station 4 – 80% Alcohol
Station 5 – 100% Alcohol
Station 6 – 100% Alcohol
Station 7 – 100% Alcohol
Station 8 – 100% Alcohol
Station 9 – Xylene
Station 10 – Xylene

All programs times were correct and conformed to laboratory SOP.

e. Laboratory had two (2) new charcoal filters on hand which were replaced during the warranty inspection. Laboratory was found not following the recommended maintenance for charcoal exchange (every 20 runs) and replacement of fume control water (every run).

f. A full End of Warranty inspection was completed on both instruments. All O-Rings on the Rotary Valves were inspected. No cracks in were found in the Rotary Valves and all O-Rings were found to be in good condition. The valves were lubricated with vacuum grease. The three Solenoid Valves for each instrument were cleaned and tightened. The aspirator cups and overflow bottles were checked for excess build up (very little). The pump diaphragms and sheets were not replaced. They were in good condition with no cracks (recommended by Sakura to be replaced annually). The manifolds on were drained; little to no build up, and the reagent lines were inspected, and found to be in good condition.

g. The instruments ran with a Routine Program overnight with a new charcoal filter in place along with new paraffin baths and no xylene fumes were detected the next morning.

Summary:

Based on the inspection performed and information gathered by Somagen Diagnostics between September 29, 2008 and October 2nd, 2008, the two VIP 5 tissue processors (s/n 52151443 and s/n 52151442) are deemed to be operational. A full inspection was performed on the system on Wednesday October 1st, 2008 where all mechanical and electrical aspects of the instrument were inspected and all were found to be within and above manufacturer's specifications, thus ruling out instrument error as the cause for excessive xylene fumes.

Somagen Diagnostics advises the laboratory to be diligent when performing charcoal and fume control water maintenance as these two are vital components of the fume management system on board the VIP 5 tissue processor. Paraffin reservoirs in the oven will evaporate xylene, which may be present in the paraffin, into the surrounding air inside the oven. This air is then processed through the degassing cycle of the VIP 5 tissue processor. In the degassing cycle the air is passed through the charcoal filters to remove xylene molecules. However, if the charcoal filters are saturated with xylene (i.e. have not been changed as per the manufacturers' recommendations of once a month or every 20 processing runs) the fume management system will not be operating at its full capacity. The fume control water operates by allowing formaldehyde and alcohol molecules to dissolve into solution and therefore the fume control water can also becomes saturated. The fume control water is recommended to be changed on a daily or every run basis. The laboratory is therefore advised to revise their SOP to reflect the charcoal and fume control water maintenance for optimal fume management.

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