Management of Microbiology Stock Final Report April 2022

Public Health Wales NHS Trust



Partneriaeth Cydwasanaethau Gwasanaethau Archwilio a Sicrwydd Shared Services Partnership Audit and Assurance Services



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Review reference:	PHW-2122-17
Report status:	Final
Fieldwork commencement:	28 February 2022
Fieldwork completion:	16 March 2022
Debrief meeting:	16 March 2022
Draft report issued:	31 March 2022
Management response received:	22 April 2022
Final report issued:	25 April 2022
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Acknowledgement

NHS Wales Audit and Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

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Executive Summary

Purpose

To provide assurance that there are adequate and effective processes in place to manage microbiology stock.

Overview

We have issued substantial assurance on this area. The matters requiring management attention include:

- The 'Management of Kits and Reagents' Standard Operating Procedure is out of date.
- Consideration be given by Finance to reconcile the accounting balance of unused, high value, microbiology stock on a quarterly basis as opposed to the current monthly arrangements.

No other recommendations or advisory points have been raised.

Report Classification

Substantial	Few matters require attention and are compliance or advisory in nature.
	Low impact on residual risk exposure.

Assurance summary¹

Assurance objectives	Assurance
1 Stock Control Procedures	Reasonable
2 Stocktaking arrangements	Substantial
3 Stock Storage and Security	Substantial
4 Stock Movement	Substantial
5 Ordering and Receipt of Stock	Substantial
6 Management Information	Substantial

¹The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

Key Matters Arising		Assurance Objective	Control Design or Operation	Recommendation Priority
1	Stock Control Procedures	1	Operation	Medium

1. Introduction

- 1.1 The management of Public Health Wales NHS Trust (the 'Trust') asked us to review the process for the management of stock.
- 1.2 Due to the pandemic, Audit Wales were unable to attend the year-end stock take for the 2020-21 financial audit. Their work reconciling information from a stock take in May 2021 to the stock value as at 31 March 2021 identified a difference, but following further work Audit Wales concluded that the balance was not materially misstated.
- 1.3 The Trust are responsible for 13 laboratories including the IP5 laboratory, three regional laboratories based in Cardiff, Rhyl and Swansea, and nine small laboratories. At the height of the pandemic there was a considerable amount of stock, including high value consumables, held at IP5, but this has since reduced. The three regional laboratories hold lower levels of stock whilst the nine small laboratories hold small levels of stock.
- 1.4 A Stock Control Review Team (SCRT) is in place and has reviewed the Standard Operating Procedure (SOP) on stock management.
- 1.5 The relevant lead for the review is the National Director, Health Protection and Screening Services and Executive Medical Director.
- 1.6 The potential risks considered in this review were as follows:
 - There are inadequate stock control procedures in place.
 - There are inadequate and uncontrolled ordering processes in place for stock.
 - There is poor physical security of stock.
 - There is limited availability and use of management information on stock.

2. Detailed Audit Findings

Objective 1: Procedures are in place to determine appropriate stock, order levels and order frequencies for stock.

2.1 The Trust has developed the 'Management of Kits and Reagents' SOP which was approved by the Head of Operations (Microbiology and Health Protection) in 2018, and details key stock management processes such as stock ordering, stock storage, routine stock checks and stock movement record keeping. The SOP is out of date and was due for review in May 2021, but Microbiology has been focusing on providing uninterrupted services and have continued to operate their Covid-19 testing facilities whilst facing unprecedented demand and pressures in light of the pandemic. (Matter Arising 1)

Conclusion:

2.2 There is a standard operating procedure in place for Management of Kits and Reagents, but it needs to be reviewed and updated as it does not reflect current arrangements. As such, we have provided reasonable assurance against this objective.

Objective 2: Appropriate arrangements are in place when undertaking a stock take.

- 2.3 Audit Wales attended IP5 in May 2021 for a full stock count and calculated the stock opening and closing balances back to March 2021. The outcome of this work identified a difference of approximately £0.28m between the stock value in the financial statements and the calculated stock value. Audit Wales recognised that this difference was not a 'material misstatement' as reconciling to the exact year-end stock figure was in part difficult due to the following limitations and variables of their calculation:
 - Stock values constantly change as stock is used each day.
 - Wastage of stock may vary due to test verification and validation of retesting of samples.
- 2.4 Even though the findings from Audit Wales were not deemed to be material the Microbiology team have reviewed and improved the stock taking arrangements in place. Ordinarily stock takes were performed at year end, however, from May 2021, the process was revised to implement additional weekly and monthly stock takes.
- 2.5 There are different types of stock held at IP5 and as per the new arrangements post May 2021, these are counted at intervals as follows:
 - Perkin Elmer High value stock used for undertaking PCR/Covid-19 testing. This stock is counted on a weekly basis.
 - Ortho Clinical Diagnostics High value stock used for research purposes. This stock is counted on a monthly basis.
 - Apparatus and general laboratory stock items such as pipette tips, testing plates, plastic jars, thistle tips etc. This stock is counted on a weekly basis
 - Low value stock stationery items and Protective Personal Equipment (PPE) including gloves, medical masks, sanitiser and sanitary bags for disposal. Stationery items are counted on a monthly basis and PPE is counted on a weekly basis.
- 2.6 The Senior Biomedical Scientists are responsible for undertaking the weekly and monthly stock takes and do this cyclically to ensure that each one performs at least one stock take throughout the month. This ensures that there is resilience within

the team so that if a member of staff is not available the stock count process can be replicated by another member of the team. We consider this to be good practice.

- 2.7 At the end of the month, the result of the stock takes for high value items (Perkin Elmer and OCD) are shared with Finance who use the closing stock balance to make an adjustment within the financial system for 'unused stock'. This adjustment ensures that all stock has been accounted for appropriately. Following the findings from Audit Wales, in May 2021 management decided that more regular stock takes and adjustments to the financial system would be necessary to ensure the stock closing values were more accurate.
- 2.8 As part of our fieldwork, we visited the laboratory (IP5) to physically witness and shadow the Senior Biomedical Scientist undertaking the weekly and the monthly stock takes. We did not identify any issues with the stock take process and note the following good practice:
 - The Senior Biomedical Scientist has developed template stock take checklists with the stock to count (both for the weekly and monthly counts).
 - Following completion of a stock take all the findings are updated on the master stock records which are securely held on spreadsheets only accessible to the Senior Biomedical Scientists, the Deputy Operational Manager, the Operational Manager and the Programme Manager.
 - Following each stock take, the results are reviewed and signed off by another member of staff (either another Senior Biomedical Scientist or the Deputy Operational Manager). All of the weekly and monthly stock take sign off sheets for 2022 to date had been reviewed and countersigned appropriately.
 - Stock takes are planned for quiet times of the week (early in the morning, end of the week etc) to ensure the least disruption as possible.
 - Staff responsible for undertaking stock takes had been shown how to complete the stock takes and update the relevant forms and spreadsheets.

Conclusion:

2.9 There are clear and robust arrangements in place for performing, recording and authorising stock takes. The Microbiology Team, following Audit Wales visit in May 2021, have implemented a robust process for recording and documenting findings from stock takes. As such, we have provided substantial assurance against this objective.

Objective 3: Stock is securely held in a manner that maximises the efficiency of the storage facilities.

2.10 Access to the IP5 laboratory is restricted to Microbiology personnel with authorised access (Staff ID cards). Storerooms and freezer rooms are not restricted, and access is available to all staff who have access to the laboratory facilities. However,

we do not consider this to be a control issue as staff need unrestricted access to the storerooms and freezer rooms to undertake their roles and responsibilities.

- 2.11 Our walkthrough of the store and freezer rooms confirmed that the space used for storing stock had been assigned a bay, isle, and shelf number. This is good stock management practice ensuring efficiency and good space use.
- 2.12 The Senior Biomedical Scientist has developed map charts for each storeroom with the assigned number location for each stock type, which helps staff know the location of items.
- 2.13 Flammable stock is securely held in a steel cargo storeroom. The keys for this storeroom are held by the Senior Biomedical Scientists supervised by the Deputy Operational Manager.

Conclusion:

2.14 Stock was securely held in manner that looked to maximise the efficiency of storage facilities available at IP5. As such, we have provided substantial assurance against this objective.

Objective 4: Transactions are recorded, and stock movements are appropriate and authorised, and stock reconciliations are undertaken.

- 2.15 As stated above in Objective 2, the Microbiology team has developed stock control spreadsheets which note the stock movements on a weekly and monthly basis. Each spreadsheet is updated by the relevant person who undertakes the stock take.
- 2.16 Our review of the stock control spreadsheets confirmed that it contained appropriate information such as batch number, stock level and expiry date.
- 2.17 Our discussion with the Senior Biomedical Scientist and the Deputy Operational Manager identified that currently there are no specific procedures for disposal of high value stock (Perkin Elmer and/or OCD). We understand that these items would rarely be wasted or disposed of as the stock tends to have a long use by date.
- 2.18 Once the monthly stock count has been authorised and the stock control spreadsheet updated, the closing stock (also referred to by Finance as 'unused stock') is shared with Finance. The Senior Finance Business Partner uses this information to reconcile the 'unused stock' levels and make an adjustment within the financial system to account for this value.
- 2.19 We understand that in the last 12 months the percentage of stock that is unused has significantly reduced. The amount of high value stock (Perkin Elmer and Ortho Clinical Diagnostic) in May 2021 totalled £7.5m, but at the time of our fieldwork in February 2022 the amount totalled £3m.
- 2.20 Given the significant reduction in the last 12 months of 'unused stock', the materiality profile has lowered. Given these findings, there is scope to review and revise the frequency of stock taking arrangements. (Matter Arising 2)

Conclusion:

2.21 The Microbiology Team has implemented a robust process of controls for recording findings from stock takes, stock movements and finance stock closing reconciliations. As such, we have provided substantial assurance against this objective.

Objective 5: Appropriate processes are in place for ordering and receiving stock.

- 2.22 The stock ordering arrangements are led by the Senior Biomedical Scientists and overseen by the Deputy Operational Manager. The finance system, Oracle, has pre-approved order limits for all members of staff. If the order exceeds a person's limit, then approval is sought from a member of staff with the relevant authority.
- 2.23 At the beginning of the pandemic, there had been a number of high value purchase orders put in place for high value stock (Perkin Elmer and OCD). This was an intentional due to the global supply chain issues and uncertainty. The Microbiology team no longer operates this way.
- 2.24 Purchase orders are raised more frequently at lower value as and when additional Perkin Elmer stock is required. Following each stock take, the levels of stock are reviewed and compared to 'trigger order' levels. These set levels take into consideration the lowest threshold of items which should be in stock to be able to continue operations until a delivery is placed, and orders received. We note that the trigger order level takes into consideration the time it usually takes the supplier to deliver these items.
- 2.25 Each time an order is placed, it is recorded on the Ordering IP5 spreadsheet to ensure that the Microbiology Team has an overview of the stock awaiting delivery. Prior to placing orders, staff refer to this Ordering IP5 spreadsheet to prevent duplicate orders if, for example, stock is yet to be delivered.
- 2.26 When goods are delivered, these are accepted into the IP5 warehouse by the warehouse staff who then notify the Microbiology Team of the arrival of the goods. The Microbiology Team scan the delivery notes and hyperlink these to the Ordering spreadsheet and sign and date each document. The delivery note is checked to ensure that the quantities and items delivered match the goods.

Conclusion:

2.27 The Microbiology Team has robust and appropriate ordering and goods receipt arrangements and processes in place. As such, we have provided substantial assurance against this objective.

Objective 6: Management information is available which is accurate, timely and relevant

- 2.28 There is no specific stock management report presented to senior management. The results/findings from each stock count are saved and can be accessed by the Operational Manager and/or the Microbiology Programme Manager.
- 2.29 We understand that if there are issues concerning stock management arrangements these can be reported directly to the Operational Manager and/or the Microbiology Programme Manager by the Deputy Operational Manager.

Conclusion:

2.30 There is no specific stock management report produced but results from all stock counts are saved and the monthly closing stock is shared with Finance. As such, we have provided substantial assurance against this objective.

Appendix A: Management Action Plan

Matter Arising 1: Standard Operating Procedures (Design)	Impact
The SOP has a review cycle of every three years, but at the time of our fieldwork the 'Management of Kits and Reagents' SOP was out of date (due for review in May 2021). We acknowledge that the Microbiology team's focus has been on providing uninterrupted services and have continued to operate their Covid-19 testing facilities whilst facing unprecedented demand and pressures in light of the pandemic.	procedures can result in
Discussions with the Deputy Operational Manager and our walkthrough of the stock management arrangements at the IP5 Laboratory facility identified that the contents of the SOP did not fully reflect the processes/arrangements in place for managing stock. The SOP states that a formal and documented stock count is to be undertaken annually with the findings shared with senior management and the Finance Department. However, stock counts and unused stock reconciliations have been undertaken monthly since May 2021. As such, the SOP is out of date and does not reflect the current arrangements.	
Recommendations	Priority
1.1a The Management of Kits and Reagents Standard Operating Procedure should be updated to reflect current arrangements and be reviewed and approved every three years in line with its review cycle.	Medium

Agreed Management Action	Target Date	Responsible Officer
ACTION: Update the Management of Kits and Reagents SOP to reflect current practices		Head of Operations

Matter Arising 2: Finance 'Unused Stock'/Closing Stock reconciliation (Operation)		Impact
Considering Audit Wales findings from their stock audit in May 2021, the Finance Department decide 'unused Stock'/closing stock value within the financial system would be reconciled and adjusted end This approach was taken as there was a large value of holding stock at the time. Most of the high had been purchased up front by the NHS to mitigate supply chain risks faced as a result of the pane	ach month. value stock	Performing monthly reconciliations and stock adjustments for immaterial accounting
We note that in the last 12 months the percentage of unused stock has significantly reduced. The high value stock (Perkin Elmer and Ortho Clinical Diagnostic) fell from £7.5m in May 2021 to £3m 2022.	transactions can become onerous and at the expense of the Finance Team which	
Given this significant reduction of 'unused stock' over the last 12 months the amount of stock is le As such, there is scope to review the current stock taking process. For example, involving Finance on basis rather than monthly. Performing monthly reconciliations at this stage may take staff time away pressing matters.	a quarterly	can focus on other tasks and duties.
Recommendations	Priority	
2.1a Management should review the frequency of the 'unused stock'/closing stock adjustment recon- light of the lower levels of stock now held.	Low	
Agreed Management Action	Target	Responsible
High stock levels have been linked directly to the Pandemic response. PCR testing has significantly fallen and likely to remain relatively low until closer to the winter period when there are expectations of an increase in overall respiratory testing.	30 June 2022	Head of Operations Deputy Director of Finance
ACTION: Due to current stock levels being in excess of materiality threshold then the stock adjustment reconciliation will continue on a monthly basis. We will continue to monitor and review the monthly closing stock position, and adjust if there is a reduction in stock levels that take us below our materiality threshold.		

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	Substantial assurance	Few matters require attention and are compliance or advisory in nature. Low impact on residual risk exposure.		
	Reasonable assurance	Some matters require management attention in control design or compliance. Low to moderate impact on residual risk exposure until resolved.		
	Limited assurance	More significant matters require management attention. Moderate impact on residual risk exposure until resolved.		
	No assurance	Action is required to address the whole control framework in this area. High impact on residual risk exposure until resolved.		
	Assurance not applicable	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate.		
		These reviews are still relevant to the evidence base upon which the overall opinion is formed.		

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non- compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.



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