RM2030_ExSeedHealth_Poster Rev.01.pdf 1 17.11.2025 12.59

External quality control with the ExSeed Home Sperm Test: Reliable at-home semen analysis to enable earlier fertility awareness

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Rationale

Male factors contribute to approximately 40% of infertility cases, yet evaluation of men in fertility assessments is often delayed or incomplete due to limited access to clinical laboratory-based semen analysis and the social stigma associated with providing samples in clinical settings.

Conventional semen evaluation often requires referral to specialized clinics, involving waiting times, and incurs costs that may further discourage timely assessment. Early, accessible assessment of sperm quality could facilitate timely interventions and improve reproductive outcomes.

Home-based semen analysis offers men the ability to monitor key sperm parameters without the logisical and costly barriers, or stigma associated with clinic visits, while maintaining sample integrity. The **ExSeed Home Sperm Test Kit** is an **innovative smartphone-based, in-vitro diagnostic device** designed to perform **home-based analysis** of key semen quality parameters, including sperm concentration, progressive motility and semen volume. The system provides clinically reliable measurements comparable to standard laboratory-based semen analysis, offering a practical approach to increase accessibility to semen testing and facilitate earlier male fertility assessment outside clinical settings.

Aim

The present work aimed to evaluate the accuracy of the **ExSeed Home Sperm Test Kit** by comparing **sperm concentration measurements** from the device with reference values obtained from the **UK National Externa Quality Assessment Service (UK NEQAS)** programme. Measurements were evaluated against WHO's 6th edition reference criteria for sperm concentration.

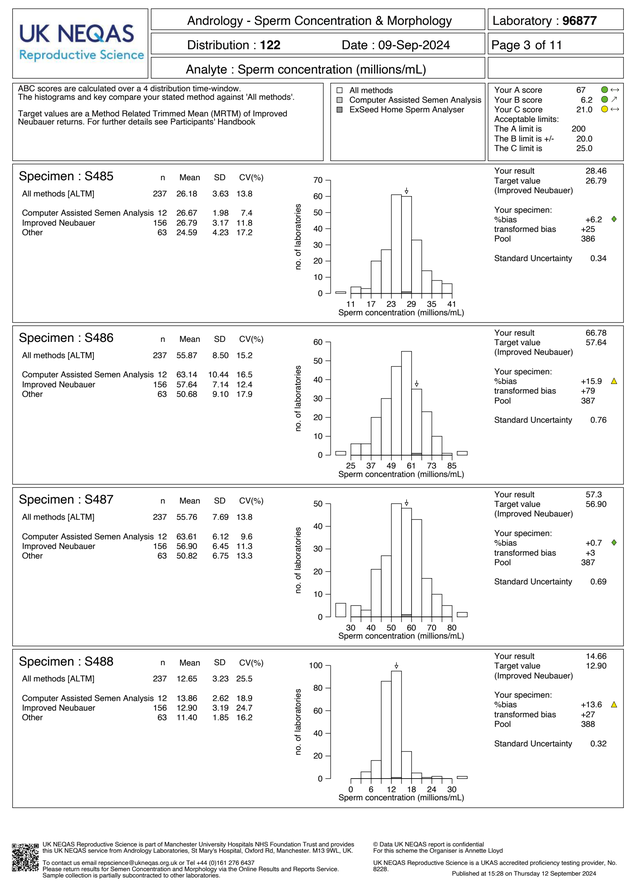
Materials & Methods

External quality control (QC) data obtained over a **2.5-year period** were evaluated through ExSeed Health's participation in the UK National External Quality Assessment Service (UK NEQAS) programme.

A total of **40 QC reference samples** provided by the UK NEQAS were analyzed using the ExSeed Home Sperm Test Kit. Measured sperm concentrations were compared with NEQAS reference values and interpreted according to WHO 6th edition reference criteria.

UK NEQAS reference samples

ExSeed Home Sperm Test Kit



UK NEQAS Reproductive Science — Andrology - Sperm Concentration & Morphology — Laboratory : **96877**
Distribution : **122** Date : 09-Sep-2024 — Page 3 of 11
Analyte : Sperm concentration (millions/mL)

ABC scores are calculated over a 4 distribution time-window.
The histograms and key compare your stated method against 'All methods'.
Target values are a Method Related Trimmed Mean (MRTM) of Improved Neubauer returns. For further details see Participants' Handbook

All methods; Computer Assisted Semen Analysis; ExSeed Home Sperm Analyser

Your A score 67 ↔ Your B score 6.2 ↗ Your C score 21.0 ↔
Acceptable limits: The A limit is 200; The B limit is +/- 20.0; The C limit is 25.0

Specimen : S485	n	Mean	SD	CV(%)
All methods [ALTM]	237	26.18	3.63	13.8
Computer Assisted Semen Analysis	12	26.67	1.98	7.4
Improved Neubauer	156	26.79	3.17	11.8
Other	63	24.59	4.23	17.2

Your result 28.46; Target value (Improved Neubauer) 26.79; Your specimen: %bias +6.2; transformed bias +25; Pool 386; Standard Uncertainty 0.34

Specimen : S486	n	Mean	SD	CV(%)
All methods [ALTM]	237	55.87	8.50	15.2
Computer Assisted Semen Analysis	12	63.14	10.44	16.5
Improved Neubauer	156	57.64	7.14	12.4
Other	63	50.68	9.10	17.9

Your result 66.78; Target value (Improved Neubauer) 57.64; Your specimen: %bias +15.9; transformed bias +79; Pool 387; Standard Uncertainty 0.76

Specimen : S487	n	Mean	SD	CV(%)
All methods [ALTM]	237	55.76	7.69	13.8
Computer Assisted Semen Analysis	12	63.61	6.12	9.6
Improved Neubauer	156	56.90	6.45	11.3
Other	63	50.82	6.75	13.3

Your result 57.3; Target value (Improved Neubauer) 56.90; Your specimen: %bias +0.7; transformed bias +3; Pool 387; Standard Uncertainty 0.69

Specimen : S488	n	Mean	SD	CV(%)
All methods [ALTM]	237	12.65	3.23	25.5
Computer Assisted Semen Analysis	12	13.86	2.62	18.9
Improved Neubauer	156	12.90	3.19	24.7
Other	63	11.40	1.85	16.2

Your result 14.66; Target value (Improved Neubauer) 12.90; Your specimen: %bias +13.6; transformed bias +27; Pool 388; Standard Uncertainty 0.32

no. of laboratories — Sperm concentration (millions/mL)

UK NEQAS Reproductive Science is part of Manchester University Hospitals NHS Foundation Trust and provides this UK NEQAS service from Andrology Laboratories, St Mary's Hospital, Oxford Rd, Manchester. M13 9WL, UK.
To contact us email nepscience@uknegas.org.uk or Tel +44 (0)161 276 6437
Please return results for Semen Concentration and Morphology via the Online Results and Reports Service.
Sample collection is partially subcontracted to other laboratories.

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Published at 15:28 on Thursday 12 September 2024

Figure 1: Assessment of the ExSeed Home Sperm Test Kit performance using external UK NEQAS reference samples.

Results

All 40 samples were correctly classified relative to the WHO 6th edition lower reference limit for sperm concentration of 16 M/mL, with four samples below and 36 above the cut-off, resulting in 100 % accuracy. Quantitatively, mean sperm concentration measured by UK NEQAS was 37.6 M/mL (range 5.1–98.2), while the ExSeed Home Sperm Test reported 38.2 M/mL(range 6.2–93.5). Method comparison showed excellent agreement, with a strong Pearson correlation (r = 0.94) and a mean bias of +0.65 M/mL, as assessed by Bland-Altman analysis, confirming that the device closely tracks reference laboratory measurements across the clinical range.

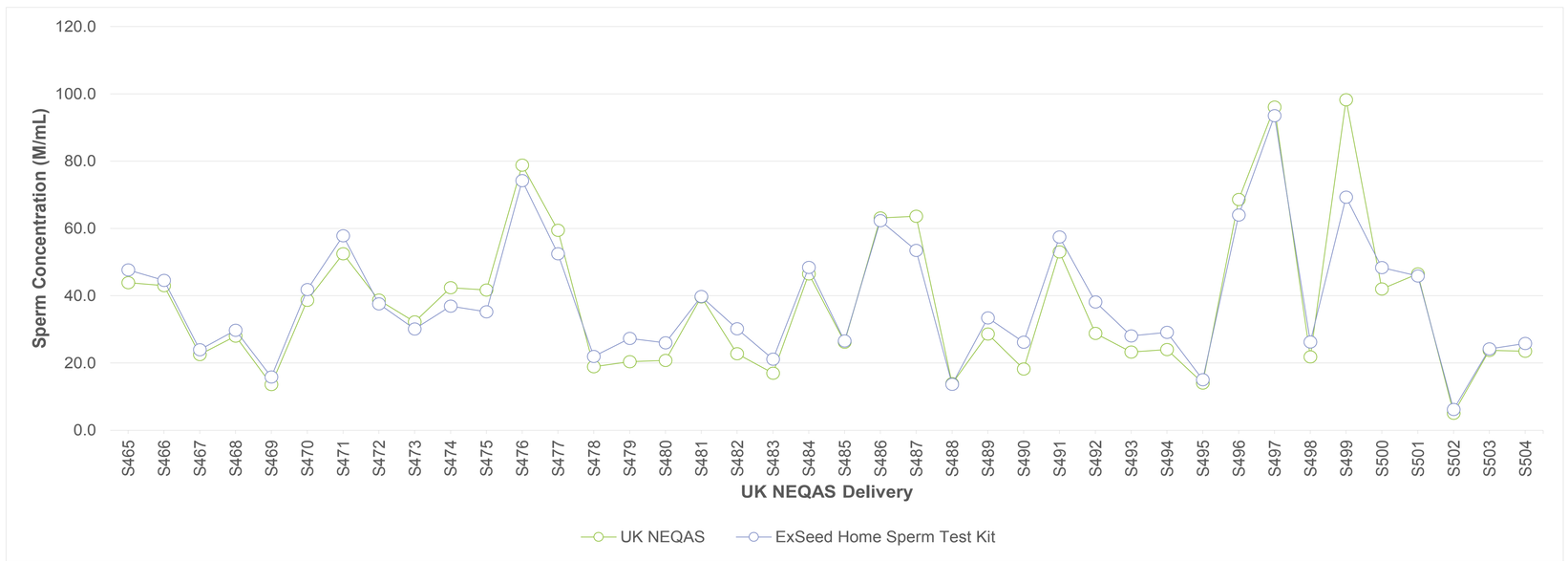

Figure 2: Comparison of sperm concentration results obtained from the ExSeed Home Sperm Test and the UK National External Quality Assessment Service (UK NEQAS).

Implications

These findings demonstrate that **the ExSeed Home Sperm Test provides robust, reproducible, and clinically comparable results** under **real-world QC conditions**. By enabling accurate, private, and accessible semen testing at home, the ExSeed system represents a significant innovation in reproductive health, reducing barriers to male fertility testing.

This work supports the use of the ExSeed Home Sperm Test Kit as a decentralized, quality-assured diagnostic tool to empower patients, optimize fertility care pathways, and relieve pressure on clinical laboratories.

About ExSeed Health

- Medical device manufacturer specializing in male reproductive health and fertility diagnostics
- Our ExSeed Home Sperm Test is a smartphone-based kit designed to assess male fertility from home. It delivers accurate and reliable results of key semen quality parameters within minutes and allows to track changes over time.
- Our ExSeed CASA Lite Human Semen Analyzer automates clinical semen analysis and provides detailed insights into sperm cell biology.
- We are committed to research, education, and innovation to advance male reproductive health globally

Learn more about us here!

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