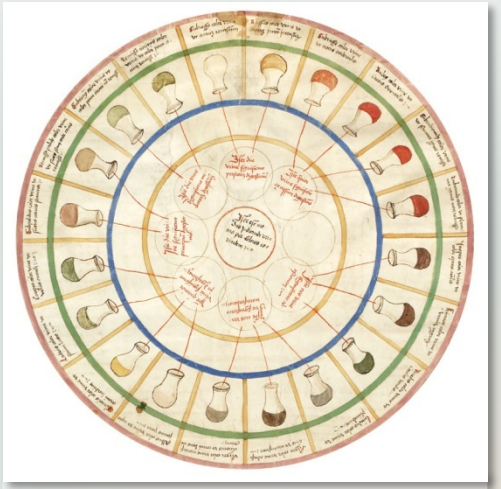
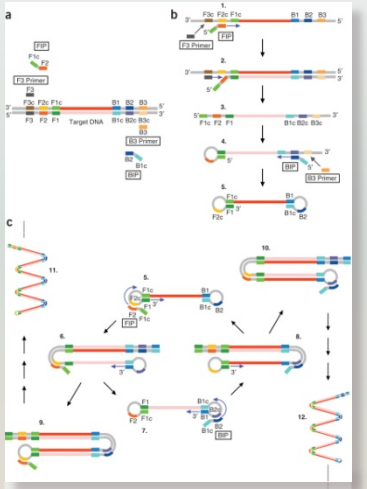




Point of Care Testing – From Sumer to Star Trek

Sheldon Campbell M.D, Ph.D., F.C.A.P.
VA Connecticut Healthcare
Yale School of Medicine

Images from, respectively, Diagnosis, the doctor and the urine glass, Lancet (1999) 354,;http://www.medicine.nevada.edu/ddl/technology/lfa.html,; and Loop-mediated isothermal amplification (LAMP) of gene sequences and simple visual detection of products, Nature Protocols 3, 877 - 882 (2008)

A Bedside Diagnosis from Urine

From a woodcut of the XVI century

From: The evolution of urine analysis; an historical sketch of the clinical examination of urine. Wellcome, Henry S. Sir, 1853-1936. London, Burroughs Wellcome [1911]

Learning Objectives

- Participants will be able to:
  - Recognize the evolution of modern Good Laboratory Practices in the history of uroscopy and other POCT.
  - Demonstrate the evolution of infectious-disease POCT from the first rapid Strep to current molecular tests.
  - Explain how Campbell's Laws impact the implementation of emerging point-of-care platforms.
  - Anticipate changes in patterns of health care and laboratory practice driven by technological change, including in POCT.

Petrus, his students and an attendant with a flask of urine, c. 1500

From Fasciculus Medicinae, Venice, C. Arrivabenus, 1522

Harvard Art Museums/Fogg Museum, Gray Collection of Engravings Fund, G5121.2

Ancient POCT: Urine Examination (Uroscopy)

CHAPTER I

UROSCOPY IN ANTIQUITY

THERE is perhaps no excretion of the human body which possesses more interest to the medical practitioner, and probably none which throws so strong a light on the organic processes of the diseased as well as the healthy body, as the urine.

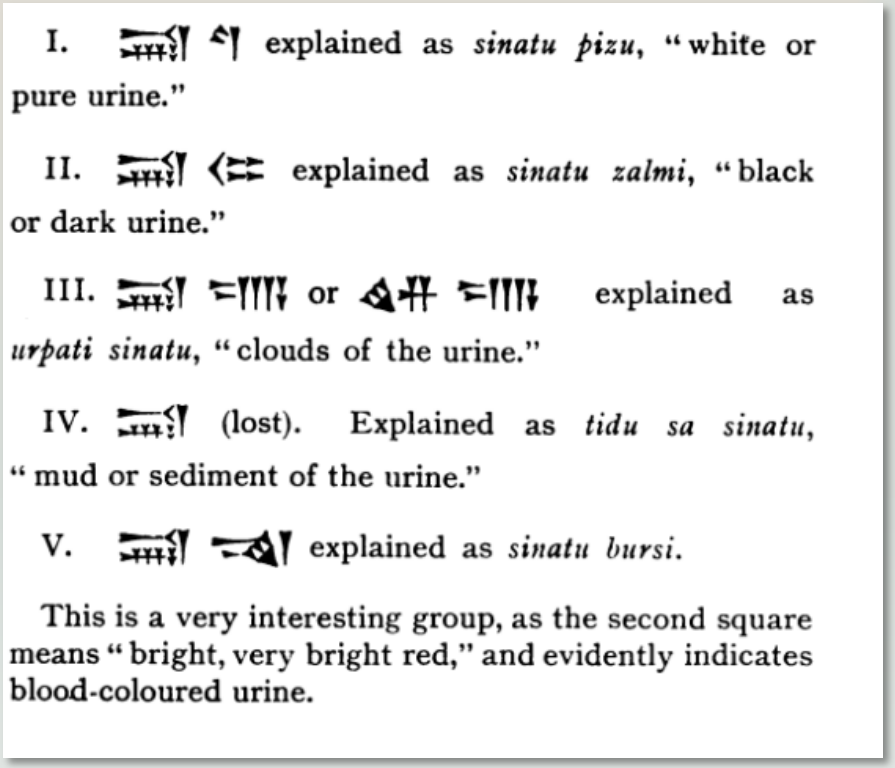
The origin of uroscopy, or the art of diagnosing disease from the inspection and examination of the urine, is practically co-eval with the genesis of the art of healing itself, and, after a careful investigation of the subject, one must conclude

Antiquity of uroscopy

From: The evolution of urine analysis; an historical sketch of the clinical examination of urine. Wellcome, Henry S. Sir, 1853-1936. London, Burroughs Wellcome [1911]

Uroscopy in the Ancient World

- A Sumerian Syllibarium (dictionary) c. 4000 BC lists body parts, and alludes to changes in color and constitution of urine observed by physicians.



I. explained as *sinatu pizu*, "white or pure urine."

II. explained as *sinatu zalmi*, "black or dark urine."

III. explained as *urpati sinatu*, "clouds of the urine."

IV. (lost). Explained as *tidu sa sinatu*, "mud or sediment of the urine."

V. explained as *sinatu bursi*.

This is a very interesting group, as the second square means "bright, very bright red," and evidently indicates blood-coloured urine.

Some Sanskrit diagnoses:

- *Iksumeha*, cane-sugar juice urine.
- *Ksuermeha*, potash urine.
- *Sonitameha*, urine containing blood.
- Pistameha, floury-white urine.
  - When the patient passes this type of urine the hair on the body becomes erect, and the urine looks as though mixed with flour. Urination is painful.
- *Hastimeha*, elephant urine.
  - "The patient continuously passes turbid urine like a mad elephant."
- *Madhumeha*, honey urine.
  - Trains of long black ants are attracted by the urine.

Hippocrates on Urine Analysis

Emphasized the importance of examining the urine with all five senses.

Thank goodness for technology.

HIPPOCRATES INSTRUCTING STUDENTS IN THE "JUDGMENT" OF DISEASE FROM THE URINE

From a woodcut of the XV century

He pointed out the effect of food and drink on the secretion, its variation in colour, odour and transparency, and taught the symptomatic and prognostic signification of these changes. "Urine is best," he states, "when the sediment is white, smooth and consistent, during the whole time until the disease comes to a crisis, for it indicates freedom from danger and an illness of short duration; but if deficient, and if it be sometimes passed clear and sometimes with a white and smooth sediment, the disease will be more protracted and not so void of danger. If the urine be reddish and the sediment consistent and smooth, the affection in this case will be more protracted than the former, but still not fatal. Farmacious sediments in the urine are bad, and still worse are the leafy; the white and thin are very bad; but the furfuraceous are still worse than these. Clouds carried about in the urine are good when white, but bad if black. When the urine is yellow and thin, it indicates that the disease is unconcocted. The most deadly of all kinds of urine are the fetid, watery, black and thick; in adult men and women the black is of all kinds of urine the worst, but in children, the watery.

Advances in Urine Analysis

- Theophilus (610-641 AD) employed heat to further the analysis of urine; arguably the first analytic technique in medicine.
- Alsahavarius (c. 1085) noted the effect of certain foods on the color of the urine, and cautioned physicians against being fooled by intentional ingestions.
- Actuarius (d. 1283) recommended the use of a graduated glass for measuring sediments.

A Greek Physician examining the Urine
and
a Diagram showing the Various
Colours of Morbid Urine
From an illuminated MS. of the XIV century

Specimen Guidelines

Ismail of Jurjani (c. end of 11th century), a Persian physician

Includes container specifications, time of collection, storage conditions, and patient instructions.

Goes on to provide detailed recommendations for examination of urine.

Uroscopy as practised by the early Persians

"The urine which is for the physician to examine," he states, "must be collected in a bottle, which must be large, transparent and clean, and if possible should be in the shape of a bladder. It should be of a large size, so as to contain the whole of the urine (24 hours), for the reason, if there be something (sediment) in it, it should be detected at once. The shape of the bottle is devised like a bladder for the reason that the urine should be in natural position as in that viscus. Urine should be well guarded against heat, cold and the sun, because extremes of temperature change its natural state, and heat makes it burn, and its thin sediments are consumed thereby. Cold makes urine congealed.

"Urine sent for examination should be that of the early morning after a good sleep. It should be passed before eating or drinking anything, because partaking of certain foods changes the colour of the urine. One should not rely upon urine that has been passed during starvation, sorrow, weakness or sleeplessness, or after coition, because above conditions change its colour. After food and wine the natural heat of the body increases for the purpose of digestion, the urine becomes colourless. Often in hot diseases it becomes white and puts the physician off his guard. After hunger, sleeplessness, sorrow and trouble, urine changes its colour, because heat (bodily) in such conditions moves about (in the body) and makes the urine appear coloured. Often one passes colourless urine after sleeplessness, because heat (bodily) is dissipated through insomnia, the urine passed is rather turbid and not clear and light, because food cannot be well digested in sleeplessness; food remains kham (uncooked, unasssimilated); that is also the reason why one gets darkish and muddy water from uncooked food.

Comprehensive QA for Uroscopy

Gilles de Corbeil, early 12th Century

Poem written in dactylic hexameter, which I dare anyone here to write a scientific publication in today.

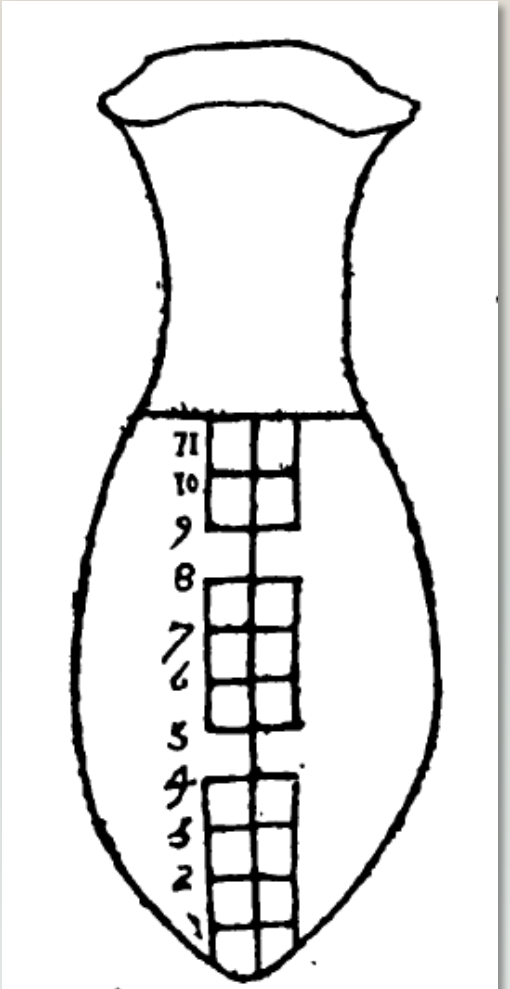
PHYSICIAN EXAMINING A SAMPLE OF URINE BROUGHT BY A PATIENT
From a woodcut of the XVI century

Gilles de Corbeil and his poetical treatise on urine

Gilles de Corbeil, who graduated at the School of Salerno at the beginning of the twelfth century, and was first physician to Phillipe Auguste, wrote an elaborate poem on the urine, entitled "Liber de urinis," which gives a good idea of the state of medical knowledge at the period in which he lived. He begins by studying the etymology of the word urine, and then, referring to the composition of this excretion, remarks that "urine is composed of the residue left in the blood and other humours in the kidneys." Next, he proceeds to lay down in detail, rules for its examination, placing, for the guidance of the uroscopist, special emphasis on the aspects, the consistence, the quantity, the nature, and the things contained therein. He enjoins the physician to take into consideration, also, the circumstances of place, the number, the time, the age, the sex, the exercises indulged in, as well as the temperament and diet of his patient.

Fletcher, 1541

- Advocated the use of the mixed urine passed during the entire day rather than a single sample.
  - "Take the whole urine and not the part such as is made at one time, but mingle not the urines made at severall times, but keep them severall both for quantity, color, and contents"
- Not quite a modern timed collection, but trending that way.



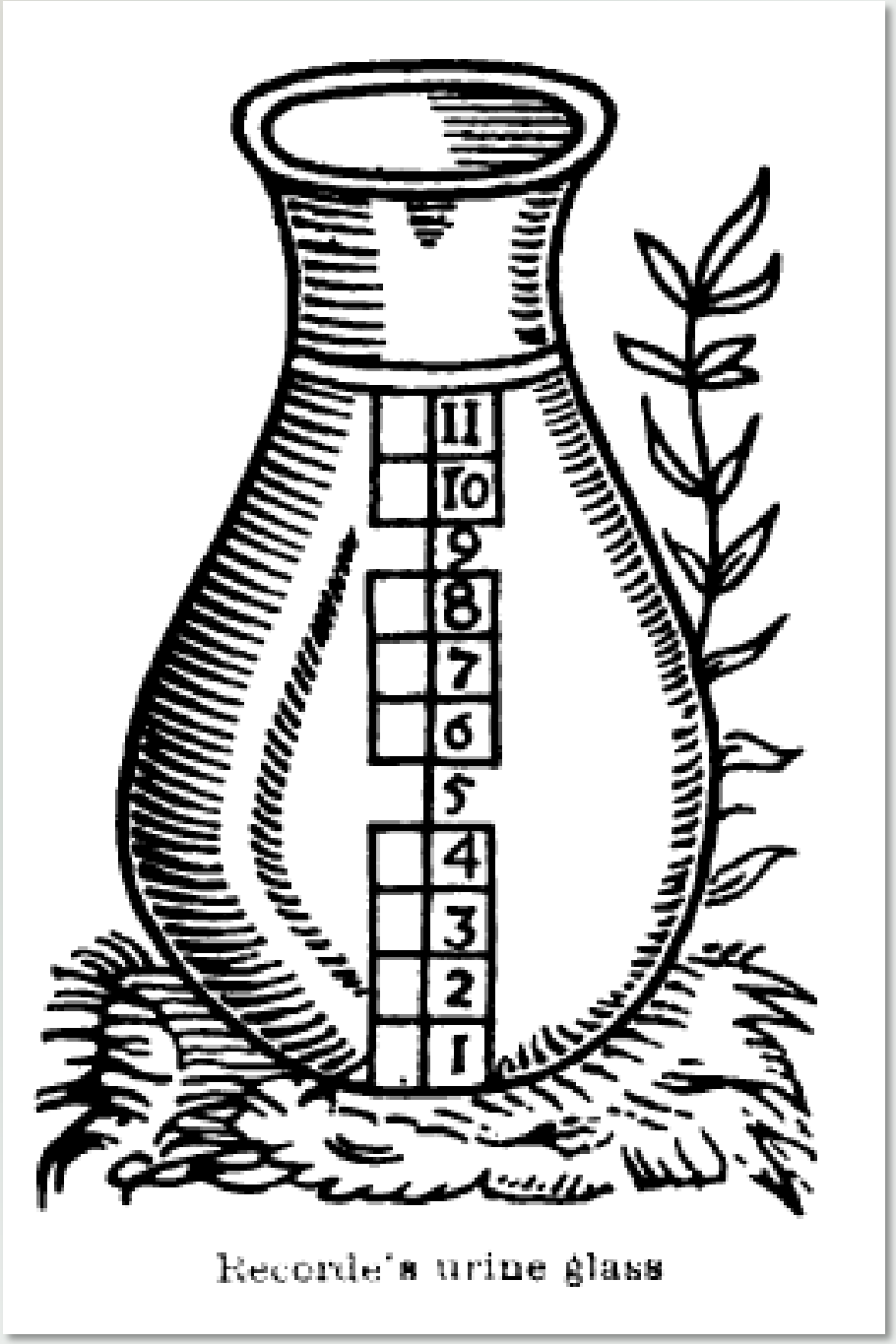
Fletcher's urine glass

Robert Recorde, 1548

Provided another detailed set of procedures for urine examination, including:

When to examine each aspect of the urine; color and consistency while still warm, sediments and contents after cooling.

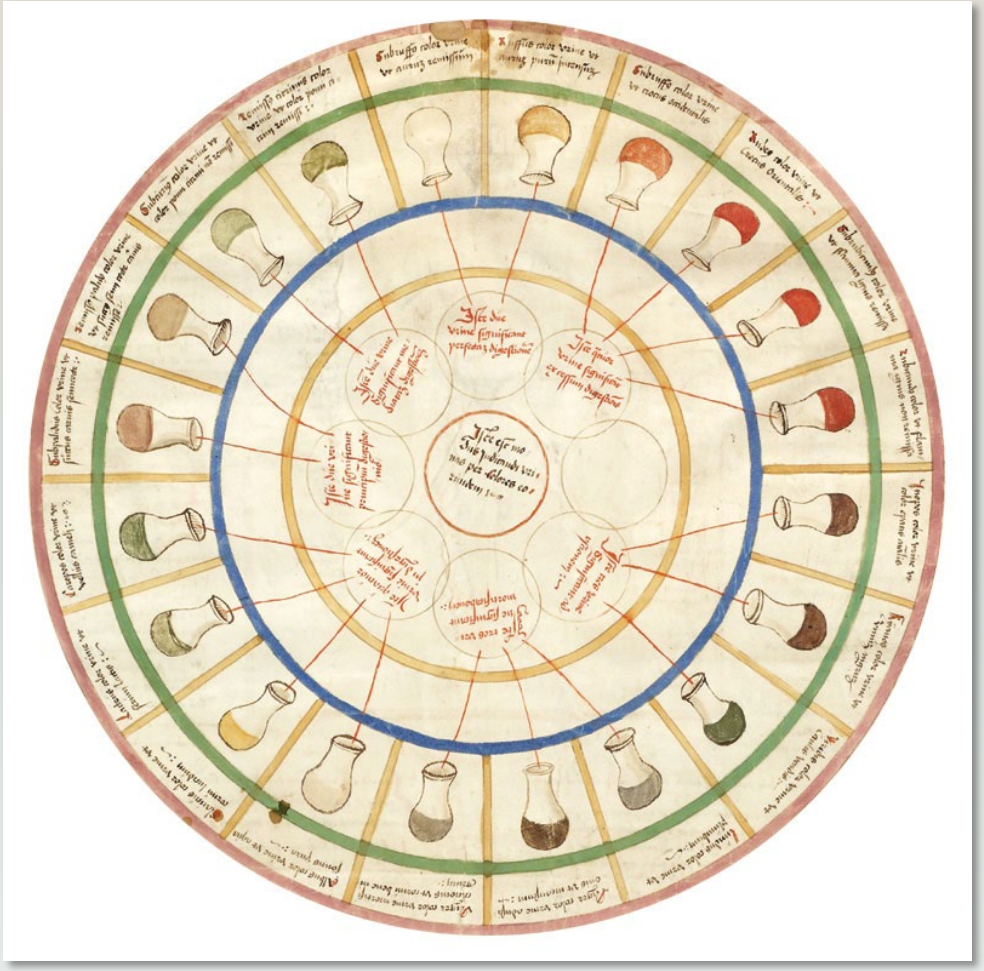
The exact nature of the viewing container (the urine-glass), and graduation of the container into segments, each used for a separate observation, e.g. the segment above the ring being used for the bubbles.



Recorde's urine glass

Historical Attempts to Comply with CLIA

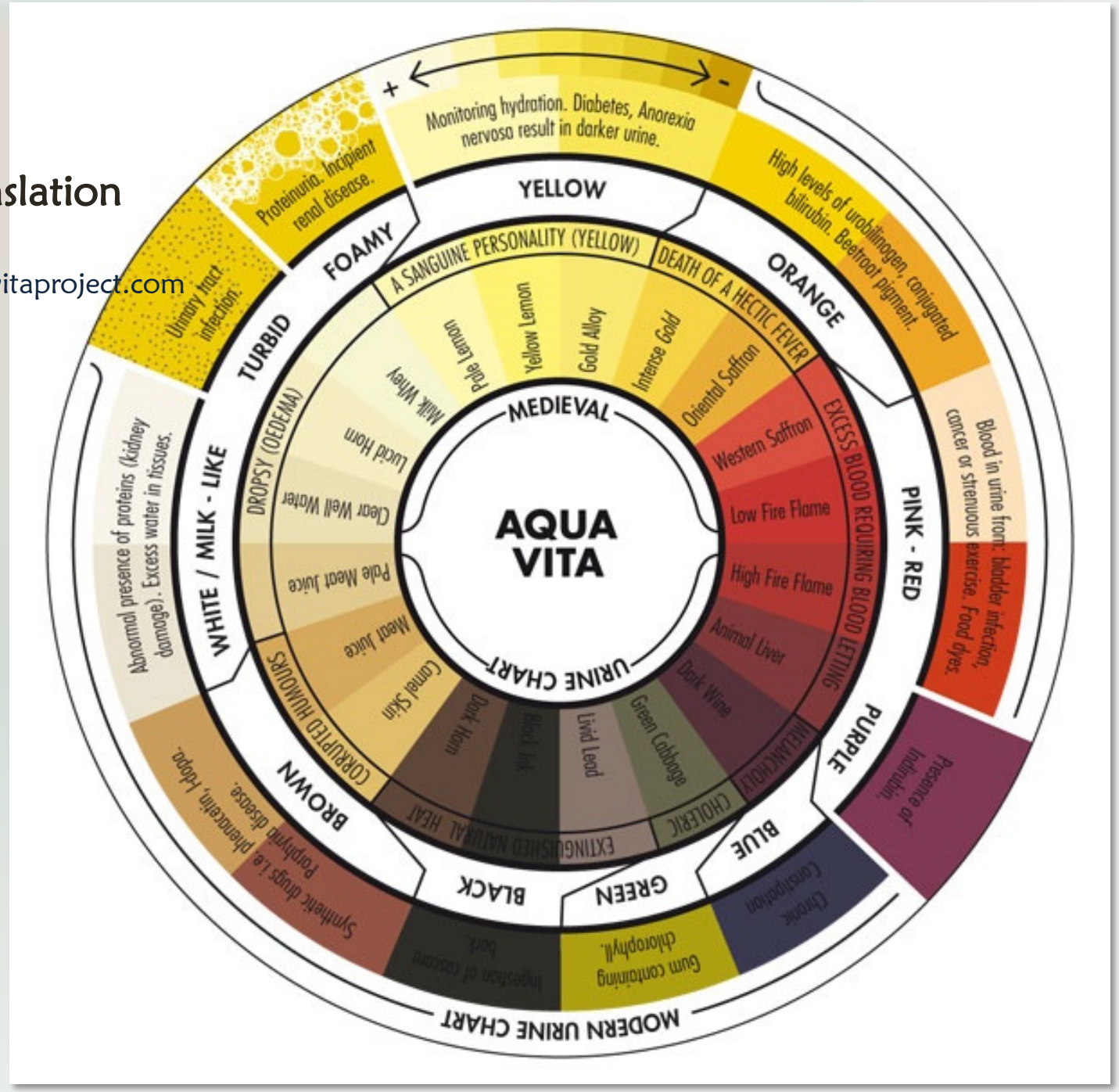
- The urine-glass disc was used as a colorimetric standard (the first ones known date from 1400 or before) in urine diagnosis.



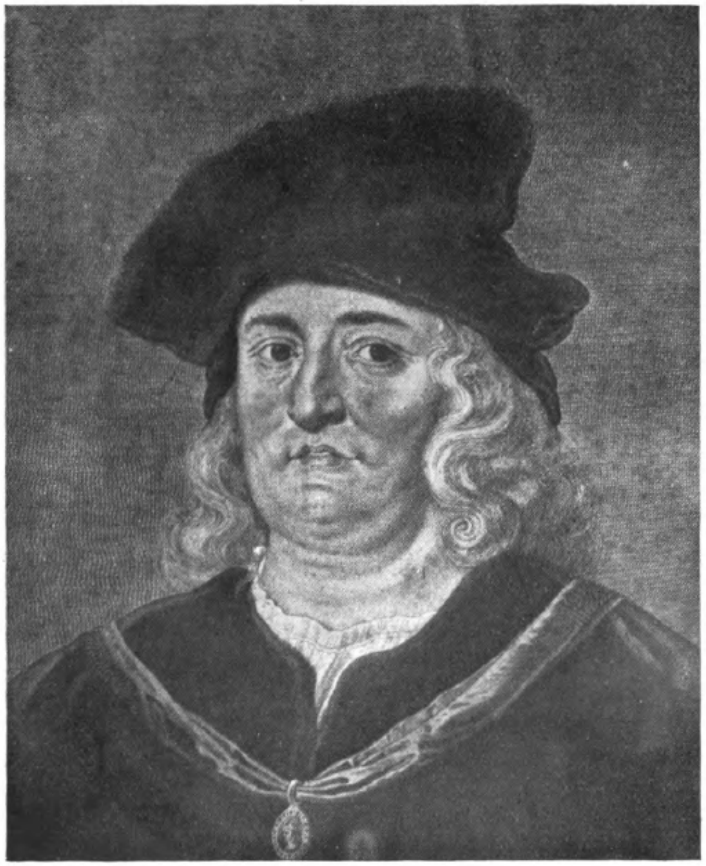
published in 1506 by Ullrich Pinder, in his book *Epiphanie Medicorum*, from http://blogs.scientificamerican.com/oscillator/2012/10/18/the-urine-wheel/

A Modern Translation

From
http://www.theaquavitaproject.com
/project.php#



Paracelsus (1493-1541) and Analytical Uroscopy



PARACELSUS
THEOPHRASTUS BOMBASTUS VON HOHENHEIM
Physician and Alchymist. 1493-1541

"Spagyric analysis"

According to his theory, disease originated from the chemicals of which man's body was formed, which were said to be mercury, sulphur and salt. Mercury, he declared, referred to the lower limbs. To discover the cause of a disease it was necessary then to resolve or divide each of these elements by a mysterious chemical process and to endeavour to find out which degree was in excess of the others in quantity. For this purpose, the urine was taken as the diagnostic agent, and was distilled and weighed. The distillate was said to correspond to the portion of the body where the disease was located, and thus its nature was indicated.

As an example, it may be stated that mercury or sulphur diseases were indicated by the vapour as it rose in the upper part of the alembic, which indicated dizziness, ear troubles and delirium, while the vapour which was deposited in the alembic was thought to be less harmful than that which escaped, especially if it came forth from the left-hand side of the cucurbite, which indicated dire events, such as apoplexy and death.

Van Helmont (1578-1644): Measurement

Measured the comparative weight – what we'd identify as the specific gravity – of urine in various conditions.

Van Helmont gives the result of his researches as follows: "One ounce of urine weigheth 600 grains, but I had a glassen vessel of a narrow neck weighing 1,354 grains, but it was filled with rain-water weighing besides 4,670 grains. The urine of an old man was found to weigh in the same vessel 4,729 grains, or to exceed the weight of the rain-water 50 grains. But the urine of a healthy woman 55 years old weighed 4,745 grains. The urine of a healthy man of 19 years old weighed 4,766 grains. But that of another young man of a like age being abstemious from drink weighed 4,800 grains. The urine of a young man 36 years old, undergoing a tertian ague with a cough weighed 4,763 grains. But the aforesaid youth of 19 years old with a double tertian had drunk little in the night aforegoing, but his urine weighed 4,848 grains, which was 82 grains more than while he was healthy.

Van Helmont urges the importance of weight in the judgment of urine

Further Advances

- In 1620, De Peiresc described rhomboidal crystals in urine; later shown to be uric acid.
- Thomas Willis (1674) distilled urine and described the components derived; also described the sweetness of urine in diabetes mellitus.
- Lorenzo Bellini (1643-1704) evaporated urine and concluded that urine was composed of ‘water, salt, and tasteless earth’.
- Boerhave (1668-1738) directly measured specific gravity; also discovered urea.
- Urea more completely described in 1771 by Rouelle the Younger.

Matthew Dobson (1772) and Diabetes

- Evaporated diabetic urine to dryness; discovered that the residue was indistinguishable from common sugar by taste, smell, or chemical treatments.

In the following year, Matthew Dobson, of Liverpool, published the results of his epoch-making experiments which he had carried out with the urine of diabetic patients. He noted that the urine of such was very transparent, of pale straw colour and sweet, and, upon placing it on one side in an open vessel, separation began to take place, and woolly clouds appeared which gradually subsided and covered the bottom of the vessel with a loose white precipitate. He observed that with longer keeping, the urine underwent vinous and then acetous fermentation. He experimented also by heating the urine to boiling point, and noted that he got no coagulation. He further tried, although without result, the addition of the mineral acids, thereby inaugurating the era of the chemical testing of urine.

Dobson's important investigations

His final experiment was that of evaporating two quarts of the diabetic urine to dryness, from which he observed that the residue he obtained was in the form of a white cake, which weighed four ounces, two drachms and two scruples. This, he states, could not be distinguished from ordinary sugar, by the taste or smell. On the addition of acid elixir of vitriol no effervescence was caused, but on the addition of a more concentrated vitriolic acid an effervescence ensued, and some pungent fumes were given off.

He introduces chemical tests

Judging from Dobson's original experiments, and especially of his use of the mineral acids as tests, he may be regarded as one of the most important pioneers in the scientific era of urine analysis.

Further Analysis of Urine

- Tests for sugar, bile, and albumin were developed during the 1800s, and their use in diagnosis of disease developed.
- Use of the microscope in examination of urine sediment also developed in 1800s.

Markwick on examination of urine

In 1847, Markwick wrote a guide to the examination of the urine which was practically the first handbook to its scientific analysis. He mentions the use of blue and red litmus paper, and calls attention to the importance of taking the specific gravity of the liquid. He estimates albumen by boiling a given quantity and weighing the residue, bile, by the addition of hydrochloric acid, and sugar, by the yeast test, or the copper test of Trommer, in which a solution of copper was added to the urine, followed by an excess of liquor potassæ, the whole of the liquid being then boiled. From this time the copper test for grape sugar became universally employed.

Creatures in the Urine

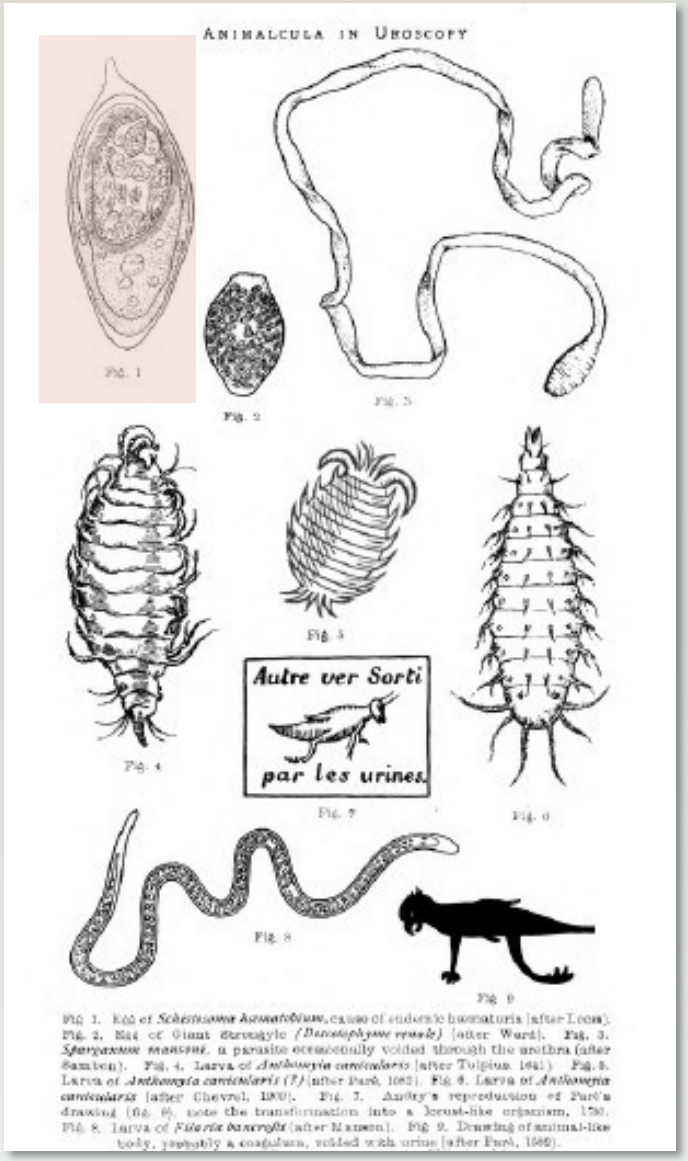
CHAPTER IV

ANIMALCULA IN UROSCOPY

The earliest record of living animals voided with urine is that mentioned by Plutarch, who observes that a friend of his, an Athenian *cphebus*, passed by way of the urethra "a pilous and many legged beast." The medical works of the Middle Ages abound with curious allusions to animalcula, fabulous and otherwise, that were observed in the urinary excretion. Bartolinus relates that a Pole passed "with gravelly urine many small, blackish, scorpion-like worms." Scalliger also mentions the voiding of "smooth, white worms, with sharp beaks, and eyes of fire," while Rondelet describes what he calls "a small dragon the size of the middle finger, provided with tail and wings," which Argentarius saw *per urinam excretum*, in 1535, at Lyons. Levin gives a description of a terrible dragon, which was passed by a woman, "with long, curved, and sharp beak, vibrating eyes, and a pointed tail." It moved very rapidly on its feet, and filled the room with its rage and hissings. Fortunately, according to the author, the patient succeeded in smothering it with her pillow.

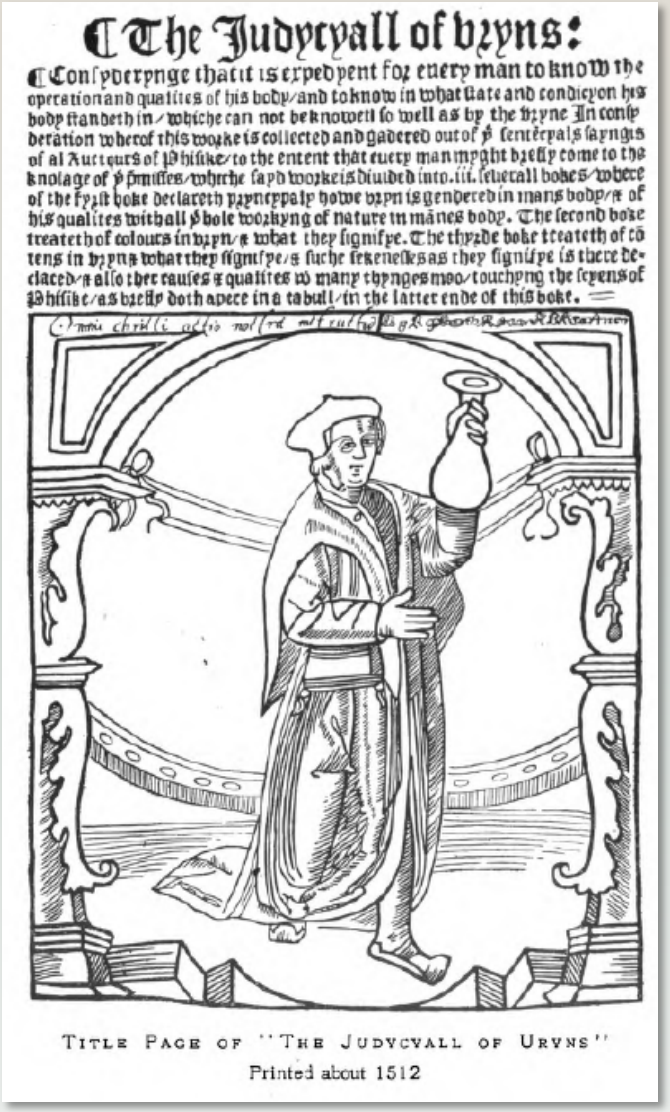
Living animals in urine

A terrible dragon passed in urine



History of Uroscopy – Lessons

- Like us, the ancient uroscopists:
  - Paid attention to pre-analytical, analytical, and post-analytical components of testing.
  - Attempted to standardize procedures and practices
  - Attempted to train, and assess and ensure competency
  - Attempted to improve the practice of their craft



Title Page of "The Judycyall of Vryns"
Printed about 1512

What has been will be again, what has been done will be done again; there is nothing new under the sun.
Ecclesiastes 1:9

An Image of Uroscopy

17th Century print by Isaac Sarabat, from the NLM History of Medicine collection.

Infectious Disease at POC

Soranus of Ephesus in the second century A.D., provided a masterful description of 'phthisis' (tuberculosis):

There is a latent fever which generally begins towards the end of the day and is relieved with the coming of the new day…

Karamanou M, Androutsos G. The masterful description of pulmonary tuberculosis by Soranus of Ephesus (c. 98-138 A.D.). Am J Respir Crit Care Med. 2012 Sep 15;186(6):571.

- To diagnose phthisis, Soranus instructed the physician to:
  - "place the phlegm over hot coals and note the odor when it has burned; the foul odor always characterizes the product of physical decomposition, as would be the case if the sputa came from a dissolution of flesh."
- In addition, he instructed the physician to place the sputa in water.
  - "Normal sputa are readily dissolved but those which are diseased remain coagulated and undissolved and sink to the bottom, for they are heavy and are the morbid product for a dissolution of the flesh"
- These analytic techniques presage our modern microbiologic and molecular analysis of expectorated sputum in the diagnosis of *M. tuberculosis* infection.

The Modern Era of POCT: Rapid Antigen Tests

- In the infectious disease world, the first antigen tests for POC use were rapid strep latex tests.
- A major advance over existing methods.
- Required a simple extraction followed by latex agglutination on a glass slide.

Gerber, M. A., L. J. Spadaccini, L. L. Wright, and L. Deutsch. 1984. Latex agglutination tests for rapid identification of group A streptococci directly from throat swabs. J. Pediatr. 105:702-705.

Latex agglutination tests for rapid identification of group A streptococci directly from throat swabs

A comparison of the accuracy and practicality of two new latex agglutination tests for the rapid identification of group A β-hemolytic streptococci directly from throat swabs was performed in a busy pediatric office. The Directigen Group A Strep Test kit had a sensitivity of 84%, specificity 99%, positive predictive value 99%, and negative predictive value 93% when compared with blood agar cultures. The Culturette Brand 10-Minute Group A Strep ID Kit had a sensitivity of 83%, a specificity 99%, positive predictive value 97%, and negative predictive value 93% when compared with blood agar cultures. When cultures with less than 10 colonies of group A β-hemolytic streptococci per plate were not considered positive, both rapid tests had a sensitivity of 95%. The Culturette Brand test required considerably less time, equipment, supplies, and skill than the Directigen test. Only the Culturette Brand test appeared to be practical for routine use in a pediatrician's office. Further investigations of the accuracy of both of these rapid tests need to be performed before either is accepted as a substitute for the throat culture. (J PEDIATR 105:702, 1984)

Michael A. Gerber, M.D., Linda J. Spadaccini, R.N., Laura L. Wright, B.S., and Larry Deutsch, M.D. *Farmington, Connecticut*

THROAT CULTURES on blood agar plates have been used to confirm the diagnosis of group A β-hemolytic streptococcal pharyngitis for more than three decades[1]; however, physicians disturbed by the 24- to 48-hour delay inherent in this procedure have sought alternative methods. For example, fluorescent antibody staining of throat swabs has been suggested as a possible substitute for throat cultures.[2] Although fluorescent antibody staining has become an acceptable method of grouping streptococci after isolation on blood agar plates, it has been unreliable when used as a primary method of identification directly from throat swabs.[3] Gram staining of smears of pharyngeal secretions has also been proposed as a possible adjunct to clinical evaluation and throat cultures in the diagnosis of GABHS pharyngitis[4]; however, this procedure requires considerable technical expertise and is relatively insensitive when compared with blood agar cultures.

From the Department of Pediatrics, University of Connecticut School of Medicine.

Submitted for publication June 8, 1984; accepted July 20, 1984.

Reprint requests: Michael A. Gerber, M.D., Department of Pediatrics, University of Connecticut Health Center, Farmington, CT 06032.

Recently several serologic methods have been developed that use either coagglutination or latex agglutination for the rapid identification of GABHS directly from throat swabs. Within the past year, two of these procedures, Directigen Group A Strep Test Kit (Hynson, Westcott, & Dunning, Baltimore, Md.) and Culturette Brand 10-Minute Group A Strep ID Kit (Marion Scientific, Kansas City, MO.), have been released commercially. We compared the accuracy and practicality of these two rapid tests in a busy pediatric office.

GABHS	Group A β-hemolytic streptococci
MCT	Micronitrous acid extraction-coagglutination test

METHODS

Children between 2 and 16 years of age seen at the Department of Pediatrics, Kaiser Foundation Health Plan of Connecticut, East Hartford, with clinical findings suggesting GABHS pharyngitis were enrolled in the study after informed consent had been obtained. Throat swabs were obtained by simultaneously rubbing two sterile rayon-tipped swabs (Culturette II, Marion Scientific) over the posterior pharynx and both tonsils (or tonsillar fossae). This procedure was then repeated so that two pairs of

Evolution of Rapid Tests

- Methodology
  - Flow-through cartridge EIA succeeded latex.
  - And was succeeded by lateral-flow tests.
- Regulation: CLIA
- Analytes (waived)
  - Antibody Tests: *Helicobacter pylori*, Hepatitis C, HIV 1&2, EBV, Lyme, RSV
  - Antigen Tests: Adenovirus, Influenza A&B, RSV, group A Strep, *Trichomonas*.

Limits of Antigen Testing

Influenza A Rapid Test Performance¶

Rapid Test	Sens%	Spec%	Compared With	Comments	Reference
Directigen	58.8	99.2	Molecular	A&B performance combined	Liao et al JCM 47(3):527-32, 2009 Mar
3M QuickVue BinaxNow	75 73 55	98 99.5 100	Culture	Archived specimens	Dale et al JCM 46(11):3804-7, 2008 Nov
BinaxNow	53		RT-PCR	2 of 237 samples were flu B pos by RT-PCr but flu A by NOW.	Landry et al JCV. 43(2):148-51, 2008 Oct
BinaxNow	61	100	RT-PCR	DFA was 81% sensitive	Rahman et al Diag Micro Infect Dis 62(2):162-6, 2008 Oct
RemelXpect BinaxNow	47.7 78.3	98.7 98	Culture	20.3/99.8 Flu B 35.9/99.9 Flu B	Cruz et al JCV 41(2):143-7, 2008 Feb
BinaxNow	52		RT-PCR	70% in days 1-3 of disease	Nilsson et al Inf Cont & Hosp Epi 29(2):177-9, 2008 Feb
Directigen	42	96	Culture		Rahman et al Diag Micro Infect Dis 58(4):413-8, 2007 Aug
BinaxNow Directigen QuickVue	73 69 67	99 100 100	RT-PCr	Sensitivity only 30% vs flu B for all	Hurt et al JCV 39(2):132-5, 2007 Jun
Quickvue	85	97	RT-PCR		Mehlmann et al JCM 45(4):1234-7, 2007 Apr.
Directigen + Quickvue + BinaxNOW	63	97	RT-PCR	Data pooled from all rapids;	Grijvala et al Pediatrics. 119(1):e6-11, 2007 Jan

Convenience sample of recent literature just before 2009 H1N1 influenza; selected by Medline search + fit to single page

A Breakthrough in Testing!

- **Credit:** Wellcome Library, London
- A physician examining a urine specimen in which a faint figure of a baby is visible, a female patient is crying and being shouted at by her angry mother, indicating that she is pregnant.
- Watercolour by I.T., 1826.

Molecular Testing for Influenza (and other pathogens…)

- Real-time methods can provide result in ~1h or so.
- Molecular methods as a class exceed culture in sensitivity (probably due to viral loss in transport)
- Detection properties do vary from system to system.
- Moderately to very expensive equipment
- Now clearly the 'gold standard'

Where We Stood in Late 2019

- Molecular testing for influenza and other respiratory viruses was standard-of-care.
- Automated readers for antigen tests improved performance somewhat, but not to the level of molecular tests.

‘The Coming Storm’, Albert Bierstadt, Public domain, via Wikimedia Commons

FDA-approved Waived Molecular Influenza Tests

- Cepheid Xpert Flu Assay
- FilmArray Respiratory Panel
- Roche LIAT Influenza A/B Assay
- Alere i Influenza A/B
- All have relatively simple workflows, 15-60 minutes to result.
- Molecular was on the way to pushing out antigen tests…

And Then Came COVID-19

Emergency Use Authorization

Share | Tweet | Linkedin | Email | Print

And a Whole Lot of Tests…

Emergency Use Authorization

Share | Tweet | Linkedin | Email | Print

03/15/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel 02/29/2020	Real-time RT-PCR	H	HCP, Patients, IFU

Showing 226 to 230 of 230 entries

Previous | 1 | ... | 6 | 7 | 8 | 9 | 10 | Next

Plenty of Molecular POC

- Effectively waived…

[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

The List 4/12/21

[1] Authorized settings include the following:

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The List 4/12/21

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- H - Laboratories certifie
  of 1988 (CLIA), 42 U.S.C
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  of 1988 (CLIA), 42 U.S.C
  complexity tests.
- W - Patient care settings

03/26/2021	Cue Health Inc.	Cue COVID-19 Test 06/10/2020	RT, Isothermal amplification, Screening	H, M, W	HCP, Patients, IFU
02/08/2021	Visby Medical, Inc.	Visby Medical COVID-19 Point of Care Test 02/08/2021	RT-PCR	H, M, W	HCP, Patients, IFU, IFU (Collect)
02/03/2021	Mesa Biotech Inc.	Accula SARS-Cov-2 Test 03/23/2020	RT and amplification	H, M, W	HCP, Patients, IFU
01/27/2021	Cepheid	Xpert Xpress SARS-CoV-2/Flu/RSV 09/24/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP, Patients, IFU for Labs, IFU for Point-of-Care
01/07/2021	Cepheid	Xpert Xpress SARS-CoV-2 test 03/20/2020	Real-time RT-PCR	H, M, W	HCP, Patients, IFU for Labs, IFU for Point-of-Care
12/23/2020	Cepheid	Xpert Xpress SARS-CoV-2 DoD 12/23/2020	Real-time RT-PCR, Pooling	H, M, W	HCP, Patients, EUA Summary
12/22/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) 10/02/2020	RT, Nested multiplex PCR, Multi-analyte	H, M, W	HCP, Patients, IFU
12/10/2020	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System 09/14/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP, Patients, IFU
09/17/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 03/27/2020	RT, Isothermal amplification	H, M, W	HCP, Patients, IFU
04/09/2021	Lucira Health, Inc.	Lucira CHECK-IT COVID-19 Test Kit 04/09/2021	RT, LAMP, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
03/05/2021	Cue Health Inc.	Cue COVID-19 Test for Home and Over The Counter (OTC) Use 03/05/2021	RT, Isothermal amplification, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test), FAQ
11/18/2020	Lucira Health, Inc.	Lucira COVID-19 All-In-One Test Kit 11/17/2020	Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)

…Including Home Molecular!

[1] Authorized settings include

- H - Laboratories certifie
  of 1988 (CLIA), 42 U.S.C
  tests.
- M - Laboratories certifie
  of 1988 (CLIA), 42 U.S.C
  complexity tests.
- W - Patient care settings

03/26/2021	Cue Health Inc.	Cue COVID-19 Test 06/10/2020	RT, Isothermal amplification, Screening	H, M, W	HCP, Patients, IFU
02/08/2021	Visby Medical, Inc.	Visby Medical COVID-19 Point of Care Test 02/08/2021	RT-PCR	H, M, W	HCP, Patients, IFU, IFU (Collect)
02/03/2021	Mesa Biotech Inc.	Accula SARS-Cov-2 Test 03/23/2020	RT and amplification	H, M, W	HCP, Patients, IFU
01/27/2021	Cepheid	Xpert Xpress SARS-CoV-2/Flu/RSV 09/24/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP, Patients, IFU for Labs, IFU for Point-of-Care
01/07/2021	Cepheid	Xpert Xpress SARS-CoV-2 test 03/20/2020	Real-time RT-PCR	H, M, W	HCP, Patients, IFU for Labs, IFU for Point-of-Care
12/23/2020	Cepheid	Xpert Xpress SARS-CoV-2 DoD 12/23/2020	Real-time RT-PCR, Pooling	H, M, W	HCP, Patients, EUA Summary
12/22/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) 10/02/2020	RT, Nested multiplex PCR, Multi-analyte	H, M, W	HCP, Patients, IFU
12/10/2020	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System 09/14/2020	Real-time RT-PCR, Multi-analyte	H, M, W	HCP, Patients, IFU
09/17/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 03/27/2020	RT, Isothermal amplification	H, M, W	HCP, Patients, IFU
04/09/2021	Lucira Health, Inc.	Lucira CHECK-IT COVID-19 Test Kit 04/09/2021	RT, LAMP, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test)
03/05/2021	Cue Health Inc.	Cue COVID-19 Test for Home and Over The Counter (OTC) Use 03/05/2021	RT, Isothermal amplification, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test), FAQ
11/18/2020	Lucira Health, Inc.	Lucira COVID-19 All-In-One Test Kit 11/17/2020	Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)

But Antigen Isn't Dead Yet

- Numerous FDA-approved antigen tests for 'waived' use.
- And several approved for home use.

04/06/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 08/26/2020	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
04/01/2021	Quidel Corporation	Sofia SARS Antigen FIA 05/08/2020	Lateral Flow, Fluorescence, Instrument Read, Serial Screening	H, M, W	HCP, Patients, IFU
03/31/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 07/02/2020	Chromatographic Digital Immunoassay, Instrument Read, Serial Screening	H, M, W	HCP, Patients, IFU
03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag 2 Card 03/31/2021	Lateral Flow, Visual Read, Non-prescription Testing, Serial Screening	H, M, W	HCP, Patients, IFU
03/24/2021	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B 03/24/2021	Chromatographic Digital Immunoassay, Instrument Read, Multi-analyte	H, M, W	HCP, Patients, IFU
03/15/2021	Access Bio, Inc.	CareStart COVID-19 Antigen test 10/08/2020	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
02/04/2021	Princeton BioMeditech Corp.	Status COVID-19/Flu 02/04/2021	Lateral Flow, Visual Read, Multi-analyte	H, M, W	HCP, Patients, IFU
01/26/2021	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read	H, M, W	HCP, Patients, IFU
12/22/2020	Quidel Corporation	QuickVue SARS Antigen Test 12/18/2020	Lateral Flow, Visual Read	H, M, W	HCP, Patients, IFU
12/07/2020	Luminostics, Inc.	Clip COVID Rapid Antigen Test 12/07/2020	Lateral flow immunoluminescent assay, instrument read	H, M, W	HCP, Patients, IFU
10/02/2020	Quidel Corporation	Sofia 2 Flu + SARS Antigen FIA 10/02/2020	Lateral Flow, Fluorescence, Instrument Read, Multi-Analyte	H, M, W	HCP, Patients, IFU
04/01/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)

But Antigen Isn't Dead Yet

02/11/2021	Ellume Limited	Ellume COVID-19 Home Test 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test), FAQ
12/16/2020	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)
03/01/2021	Quidel Corporation	QuickVue At-Home COVID-19 Test 03/01/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, Patients, IFU, IFU (Home Test)
03/31/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
04/01/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)

Home Testing? Not Quite Yet…

All covid test

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Condition
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Coronavirus protection
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Sponsored

DxTerity COVID-19 Saliva at-Home Collection Kit with Prepaid Express Return Shipping and Laboratory PCR Testing (10-Pack)

4.5 out of 5 stars 247

$1,000.00 ($100.00/Item) FSA or HSA eligible

FREE Shipping

Rapid COVID-19 Antibody Test - FDA EUA Authorized & Made in USA

Available to some CLIA certified labs with an Amazon Business account.

CareStart COVID-19 Antigen Test: Rapid, Sensitive Point-of Care Test to detect Active SARS-CoV-2 Infection in 10 Minutes - EUA Authorized and CLIA-Waived for Lower Nasal Collection (12,800 Tests)

empowerDX at-Home COVID-19 Nasal PCR Test, FDA Authorized (Home-Collected)

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$89.99 FSA or HSA eligible

FREE Shipping

SCIENCE ADVANCES | RESEARCH ARTICLE

CORONAVIRUS

Test sensitivity is secondary to frequency and turnaround time for COVID-19 screening

Daniel B. Larremore[1,2]*, Bryan Wilder[3], Evan Lester[4,5], Soraya Shehata[5,6], James M. Burke[4], James A. Hay[7,8], Milind Tambe[3], Michael J. Mina[7,8,9]*†, Roy Parker[2,4,6,10]*†

The COVID-19 pandemic has created a public health crisis. Because SARS-CoV-2 can spread from individuals with presymptomatic, symptomatic, and asymptomatic infections, the reopening of societies and the control of virus spread will be facilitated by robust population screening, for which virus testing will often be central. After infection, individuals undergo a period of incubation during which viral titers are too low to detect, followed by exponential viral growth, leading to peak viral load and infectiousness and ending with declining titers and clearance. Given the pattern of viral load kinetics, we model the effectiveness of repeated population screening considering test sensitivities, frequency, and sample-to-answer reporting time. These results demonstrate that effective screening depends largely on frequency of testing and speed of reporting and is only marginally improved by high test sensitivity. We therefore conclude that screening should prioritize accessibility, frequency, and sample-to-answer time; analytical limits of detection should be secondary.

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SCIENCE ADVANCES | RESEARCH ARTICLE

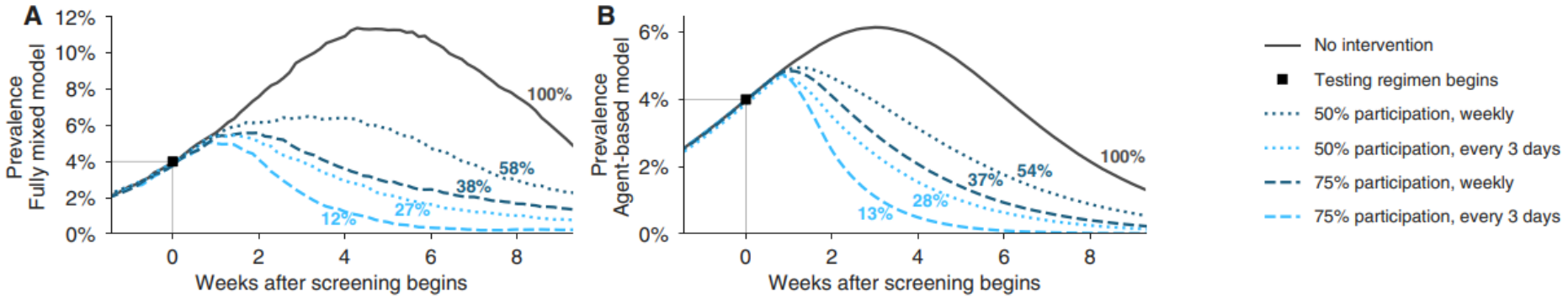


Fig. 6. Repeated population screening suppresses an ongoing epidemic. Widespread testing and isolation of infected individuals drive prevalence downward for both (**A**) the fully mixed compartmental model and (**B**) the agent-based model. Time series of prevalence, measured as the total number of infectious individuals, are shown for no intervention (solid) and population screening scenarios (various dashed lines; see legend) for individual stochastic simulations. Screening began only when prevalence reached 4% (box), and time series are shifted such that testing begins at $t = 0$. Scenarios show the impact of a test with LOD 10^5, no delay in results, and with 10% of samples assumed to be incorrectly collected (and therefore negative) to reflect decreased sensitivity incurred at sample collection in a mass testing scenario. Annotations show total number of post-intervention infections, as a percentage of the no-intervention scenario, labeled as 100% (see fig. S8 for identical simulations using a test with LOD 10^6).

So, Where Are We?

- Molecular POCT for respiratory viruses is well established and standard of care.
- How this sorts out post-pandemic remains to be seen.
- Will antigen tests persist?
  - For future pandemics?
- Where will POCT be performed?
- How will POCT enable changes in systems of health care?

From an Oil Painting by Teniers

Where are we going?

- I've thought about this a lot.
- Derived Campbell's Laws of POCT
- Two Laws, with inpatient and outpatient corollaries
  - Feedback encouraged.
  - Peaper DR, Durant T, Campbell S. Distributed Microbiology Testing: Bringing Infectious Disease Diagnostics to Point of Care. Clin Lab Med. 2019 Sep;39(3):419-431.

Campbell's First Law of POCT

- Nobody ever went into Medicine or Nursing **because they wanted to do lab tests.**
  - I can't document this with a literature citation, but it has high face-validity.
  - Anecdotally, our nurses/docs have hated glucose monitoring (still done but loathed), ER troponins (tried, failed), and rapid HIV (tried, failed).

Campbell's Second Law of POCT

- No POC test is easier than **checking one more box on the laboratory order form.**
  - Waived tests are easy, but much, much harder than checking one more box on a form you already filled out.
  - A lot of simple, rapid tests end up being *done in the lab*.

Campbell's Laws: Inpatient Corollaries

- An inpatient POC test is useful only if:
  - The time for transport to the lab for THAT SINGLE ANALYTE significantly and negatively impacts care, OR
  - The test is performed on an easily-obtained sample (e.g. fingerstick blood) more frequently than routine blood draws are obtained.

Campbell's Laws: Outpatient Corollaries

- An outpatient POC test is useful only if:
  - The test result is available during the patient visit AND a decision can be made or action taken on the basis of it **without waiting for other lab/radiology results**, OR
  - If you can make money doing it.

Campbell's Laws Example: Primary Care HIV Testing

- **June 8, 2010: Provider A:** "Sheldon, has rapid testing been considered to prevent this problem? Would this be feasible? Might allow us to expand testing to highest yield sites (i.e. the ER)…"
- **July-October 2010:** Set up program, created templated progress notes, ordered kits, trained 20+ Primary Care providers to do rapid HIV tests.
- **October 2010-January 2011:** Number of rapid HIV tests performed: **1**
- **January 2011: Provider B:** "Even though I am one of the biggest proponents, I have only done one, and that was for another provider who didn't know how to do it. I don't see people clamoring to do the test. I'm interested in Provider A's thoughts."
- **Response, Provider A:** "We have had very little use in <our clinic>. I think that it's so easy to send the pt for bloodwork that there is not much demand."
- **January 7, 2011, POCC:** "Next week I will be coming around to the Primary Care areas to collect the HIV kits. Please have them easily accessible. **Thank you and have a pleasant weekend.**"

Campbell's Outreach / Developing-World Corollaries

- Sometime's there's no lab-order form.
- Sometimes there's no nurse.
- Sometimes there's no refrigeration, power, or lights.
- Campbell's Laws should not be applied outside of a healthcare environment where the basic terms apply.

Where is POCT done?

Table 1
Microbiological POC in various environments

Care Setting	Clinical Environment	Types of Infections and Problems Seen	Turnaround Time for Impact	Other
Inpatient	Clinical laboratory on-site; often clinically complex patients.	Sepsis; HAI.	Transport time to laboratory has to be long enough to make it worth doing the test at the POC.	Wide range of potential pathogens in many cases.
Emergency	Clinical laboratory on-site	Acute infectious syndromes; some screening.	Test turnaround time strongly impacts throughput.	Tests that can speed discharge strongly favored.
Urgent care	No dedicated laboratory; test availability impacts scope of care available. Space and personnel limited. Volume of testing must justify capital expenses.	Acute infectious syndromes.	Test turnaround time strongly impacts throughput.	Availability of some tests may allow expansion of scope of care available on-site.
Ambulatory	POL on site, or only CLIA-waived tests. Space and personnel limited. Volume of testing must justify capital expenses.	Common health maintenance, screening, and acute ambulatory illnesses.	Test results must be available during the encounter to streamline care.	
Telemedicine	Laboratory may or may not be on-site, depending on the telemedicine model.	Common health maintenance, screening, and acute ambulatory illnesses.	Depends on care model.	Evolving models for telemedicine. In some cases will be linked to other services—pharmacy, imaging. Extent of laboratory tests available at POC may impact scope of care.
Outreach	Specific programs, targeting particular diseases or vulnerable populations. No on-site laboratory; limited, often temporary space.	STI; HIV, HCV.	Rapid—30 min or less for success.	
Home	Patient centered; clinical and interpretive support limited.	STI; acute infectious syndromes; chronic disease screening.	Somewhat flexible; some mail-in testing has been successful.	An evolving area; will expert systems increase the possibilities for home testing?

Abbreviations: HAI, healthcare-associated infection; HCV, hepatitis C virus; HIV, human immunodeficiency virus; POC, point-of-care; POL, physician's office laboratory; STI, sexually transmitted infection.

Strengths and Weaknesses…

Strengths	Weaknesses
• **Everything everyone loves about POC** • **Not a novel concept to MDs and Pts; accustomed to GAS and Flu Ag tests** • **Current state of the art assays (e.g. NAAT, more sensitive Ag assays) have improved performance over past** • **Some POC NAAT comparably sensitive to culture and lab-based methods** • **Many clinically relevant specimens readily available: urine, mucosal swabs, whole blood**	• Instrumentation costs • Assay / Reagent costs • Specimen type restrictions (e.g. eSwab v. conventional swab) • Serum or plasma beyond POC scope • Limited ID conditions where AST is not relevant • Quality of testing performance by non-laboratory staff. • Arbitrary / limited menus limit clinical impact • Small number of analytes per platform limit scaleability

Opportunities and Threats

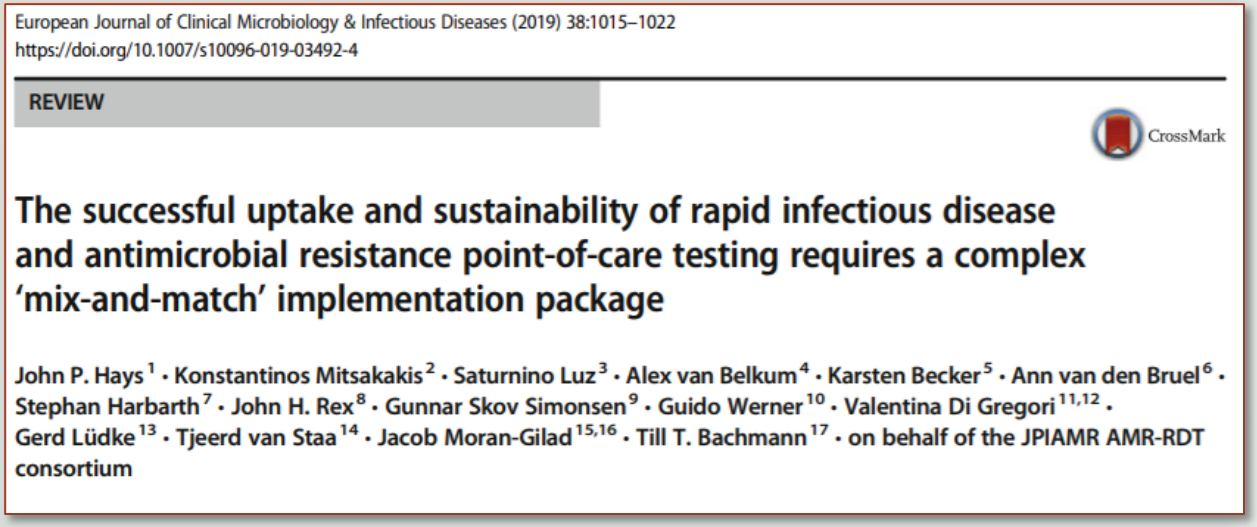
Opportunities	Threats
• **Continuing advances in testing: NAAT workflow, TAT, "Lab on a Chip"** • **Antimicrobial stewardship (AMS) gaining increased importance nationally with regulatory bodies** • **Development of biomarkers for AMS → Negative Predictive Value** • **Development of new antivirals to broaden clinical actions (e.g. RSV)** • **Implementing replacement tests at specific, off-site clinics (e.g. public health / STI clinics)** • **Ability to facilitate new models of care** • **Microbiology laboratory consolidation may necessitate more local infectious disease testing**	• Changes in reimbursement models • Inertia in physician offices • Theranos-effect → Disproportionally increased scrutiny of assays / methods and/or disproportionate fear of regulatory oversight for novel tests / methods • Turf wars between pharmacies, urgent cares, offices, EDs and potential regulation

Informatics and the Future of POCT

- As with every part of medicine, informatics is going to be central to POCT.
  - Computer vision will enable new sorts of devices; automated and remote microscopy.
  - Connectivity will allow analytic devices to draw on centralized computing resources for interpretation of complex data e.g. NGS sequence data.
- Decentralized testing models, especially for infectious diseases, will require systems to make the data available to providers and public health.
- This will require:
  - Standards for data handling
  - Best practices and probably new regulations for privacy and security.
  - Practices for verification of AI applications and distributed testing systems.

Future of POCT – Theranos?*

- Decentralizing testing will be essential for decentralized models of health care
- But will require more than just technology
  - POC Testing
  - Imaging and vital signs
  - IT Support
  - Changes in training and organization
  - Reimbursement
  - And more…



European Journal of Clinical Microbiology & Infectious Diseases (2019) 38:1015–1022
https://doi.org/10.1007/s10096-019-03492-4

REVIEW

CrossMark

The successful uptake and sustainability of rapid infectious disease and antimicrobial resistance point-of-care testing requires a complex 'mix-and-match' implementation package

John P. Hays[1] · Konstantinos Mitsakakis[2] · Saturnino Luz[3] · Alex van Belkum[4] · Karsten Becker[5] · Ann van den Bruel[6] · Stephan Harbarth[7] · John H. Rex[8] · Gunnar Skov Simonsen[9] · Guido Werner[10] · Valentina Di Gregori[11,12] · Gerd Lüdke[13] · Tjeerd van Staa[14] · Jacob Moran-Gilad[15,16] · Till T. Bachmann[17] · on behalf of the JPIAMR AMR-RDT consortium

Clinical Chemistry 64:8
1136–1142 (2018)

Q&A

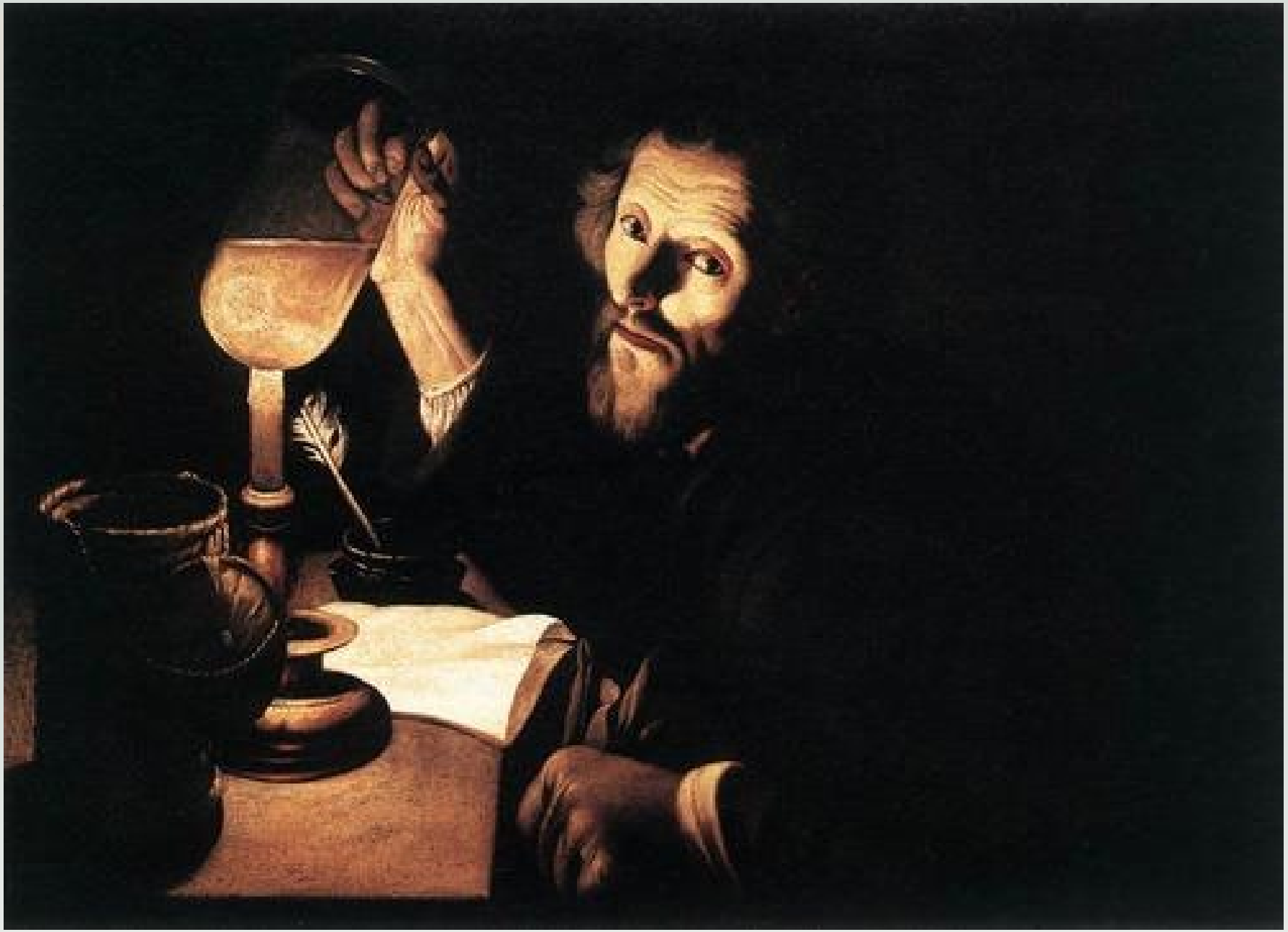
There's No Place Like Home:
Exploring Home-Based, Acute-Level Healthcare

Moderators: Michelle L. Parker[1] and Paul M. Yip[1,2*]
Experts: Linda V. DeCherrie,[3] Christian Escobar,[4] Anna K. Füzéry,[5] Christopher P. Price,[6] and Andrew St John[7]

*Only without the hype, fraud, lies and crazy.

Recommendation

- "Point-of-care testing, especially those analyses that are conducted at the patient's bedside, in a physician's office, or in a clinic, is a growing trend in health care, and clinical microbiology professionals should prepare for this future reality. Clinical microbiologists must ensure that the individuals who perform point-of-care testing understand how to interpret the results. Clinical microbiologists should be called upon to help select the assay targets, advise on test formats, and participate in clinical trials."
- From "Clinical Microbiology in the 21st Century: Keeping the Pace". American Academy of Microbiology, 2008. Available on-line at: http://www.asm.org/academy/index.asp?bid=58445



Hot Off The Presses

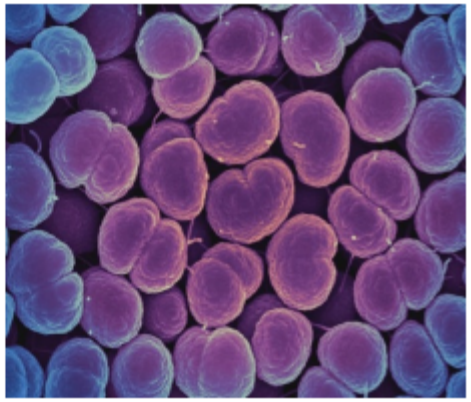
CLIA Waiver in Hand, Binx Health Targeting Retailers, Urgent Care Centers With STI Tests

Apr 08, 2021 | Leo O'Connor

Premium ***Save for later***

NEW YORK — Having achieved CLIA waiver, Binx Health expects to soon announce a collaboration with an undisclosed retail chain to offer its point-of-care platform and sexually transmitted infection tests, reflecting a broader trend toward near-patient detection in STI testing.

The diagnostic test developer recently became the first firm to obtain a US Food and Drug Administration CLIA waiver for a molecular point-of-care instrument, Binx io, and tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Its waiver comes as physicians treating STI infections have been eagerly awaiting a high-sensitivity molecular platform that can provide results in around 30 minutes and enable treatment in a single visit to the clinic, according to some STI disease testing experts.



Courtesy of NIAID/Wikimedia
Neisseria gonorrhoeae bacteria

The Future, Perhaps

EMPOWERING PERSONAL HEALTHCARE.

$10 MILLION

Prize Purse

The Qualcomm Tricorder XPRIZE was a $10 million global competition to incentivize the development of innovative technologies capable of accurately diagnosing a set of 13 medical conditions independent of a healthcare professional or facility, ability to continuously measure 5 vital signs, and have a positive consumer experience.

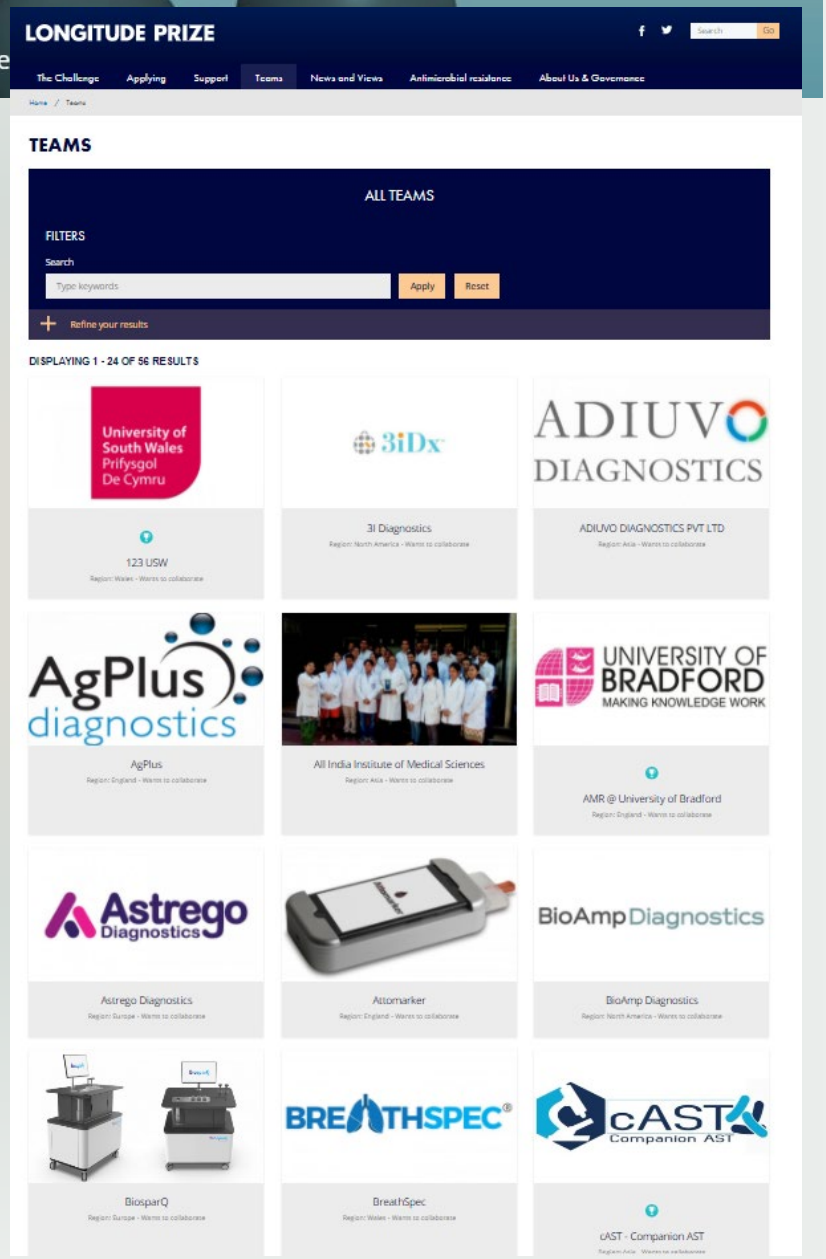
THE CHALLENGE: REDUCE THE USE OF ANTIBIOTICS

How can we prevent the rise of resistance

REGISTER YOUR TEAM

The Longitude Prize is a £10 million prize fund with an £8 million pay out that will reward a competitor that can develop a point–of–care diagnostic test that will conserve antibiotics for future generations. The test must be accurate, rapid, affordable and easy to use anywhere in the world.

Register here



Acknowledgements

- For information on uroscopy:
  - Melissa Grafe, Ph.D.
    John R. Bumstead Librarian for Medical History
    Cushing/Whitney Medical Library, Yale University
  - The evolution of urine analysis; an historical sketch of the clinical examination of urine. Wellcome, Henry S. Sir, 1853-1936. London, Burroughs Wellcome [1911].
    - Of this 305-page monograph, only the first 92 pages pertain to uroscopy; the rest consists of advertisements for Wellcome products.
- FDA waiver requirements from a slide provided by Dr. Barbara Robinson-Dunn.

During the fifteenth century quack uroscopists abounded in every land. These charlatans, who travelled the country on a pony or nag, with the urine basket slung on the arm, preyed on the credulity and ignorance of the people. With a glib tongue they made them believe that they could diagnose every disease known under the sun, as well as prognosticate all kinds of events, from a glance at the urine.