



# Ecoli Dx at a Glance

Development – Manufacture – Sale – Support Independent company, part of DYNEX group

- 20+ years of history
- 20+ professionals
- 30+ distributors

European based, worldwide standards

ISO 13845:2016 certified

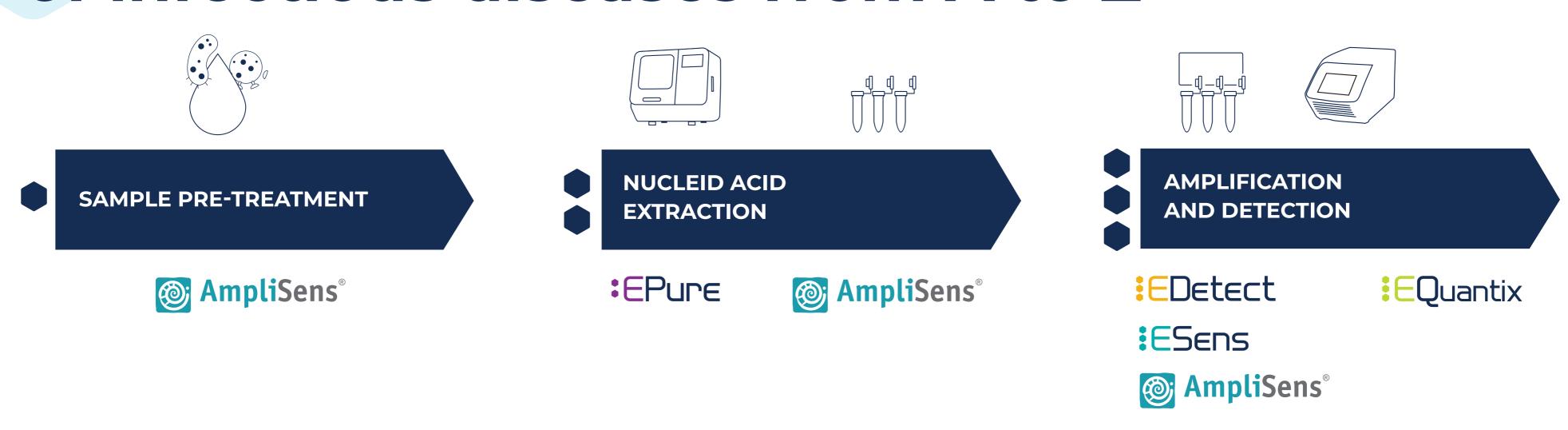
## 200+ products

- Real-Time PCR kits for human diagnostics (mainly infectious markers)
- Nucleic acid extraction kits
- Associated instrumentation and automation





# Complete solution for PCR diagnostics of infectious diseases from A to Z



- Large investments to R&D
  - Transition to in-house production
  - Robust development pipeline





- Developed and produced by the CRIE in Moscow
- Ecoli Dx is the authorized representative all over the world, with exclusivity in EU
- 100+ Real-Time PCR kits
  - A to Z of all infectious diseases and genetic markers
  - Known for their high sensitivity, specificity, and reasonable pricing
  - CE IVD certification of all previously CE IVD marked PCR kits expired
    - all of them available as RUO now
- Supplementary PCR reagents and manual extraction kits
  - Certification had been updated and available as CE IVD-R marked

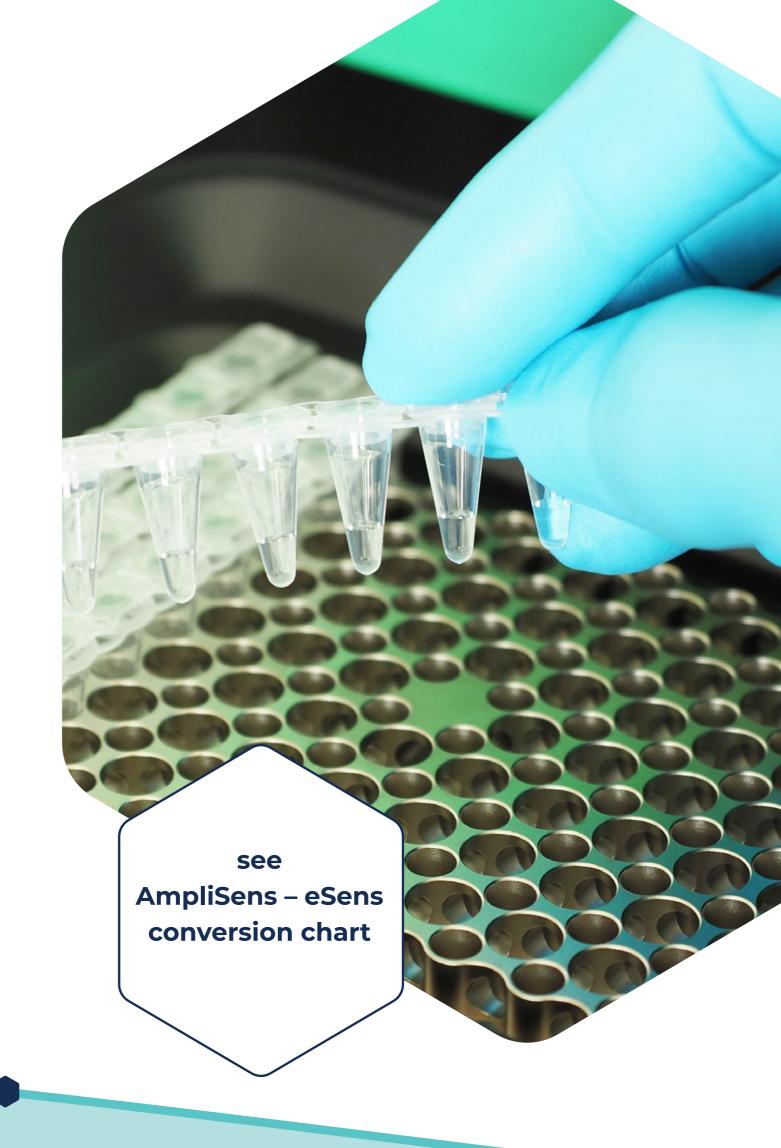


## eSens introduction

- Produced by Ecoli Dx near Prague in CZ
- "European AmpliSens"
  original AmpliSens® chemistry
  - The same polymerases
  - The same primers, probes and solutions
  - The same protocols
  - Only different packaging, labeling and documentation

**CE IVD-D marked** → Seamless transition AmpliSens® to eSens

- Maintain AmpliSens workflow unchanged while retaining CE IVD compliance
- Except PCR kits classified in group D according to IVDR criteria, which are supplied as RUO now
- 80+ Real-Time PCR kits
  - A to Z of all infectious diseases and genetic markers
  - Keeping AmpliSens performance and reasonable pricing





## eSens remarks

- eSens NA kits"NA" for Non-AmpliSens chemistry
  - eSens NA RespiViral Multiplex
  - eSens NA SARS-CoV-2/Influenza A/B Multiplex
  - eSens NA SARS-CoV-2/SARS-CoV Multiplex
  - eSens NA Mycosis Multiplex
- C. trachomatis or CMV detection available as RUO only
  - IVD certification valid only for other parameters in the multiplex assays
  - Additional instructions for the RUO detection of CT or CMV not included in the IFU
  - Application notes available separately
- PCR kits classified in group D according to IVDR criteria are supplied as RUO now
  - kits targetting SARS-CoV-2, CCHFV, EBOV Zaire, Plasmodium sp., B. anthracis





Inquire the new equivalent eSens kit					
S3808B	eSens Leptospira QL PCR kit				
S3003A	eSens Mycoplasma genitalium QL PCR kit				
S3307B	eSens Legionella pneumophila QT PCR kit				
S3000A	eSens Neisseria gonorrhoeae QL PCR kit				
S3305B	eSens MTC QL PCR kit				
S3048A	eSens Ureaplasma/M.genitalium/M.hominis Q_PCR kit C.trachoma				
S3050A	eSens N.gonorrhoeae/M.genitalium/T.vagina s QL PCR kit C.trachoma				
S3542B	eSens Escherichioses QL PCR kit				
S3049A	eSens N.gonorrhoeae /M.genitalium QL PCR kit C.trachoma				
S3002A	eSens Trichomonas vaginalis QL PCR kit				
S3044A	eSens Florocenosis/Bacterial Vaginosis QT PCR kit				
S3045A	eSens Florocenosis/Mycoplasmas QT PCR kit				
S3809A	eSens Streptococcus agalactiae QT PCR kit				
S4300A	eSens MRSA QT PCR kit				
S3005A	eSens Gardnerella vaginalis QL PCR kit				
S3043A	eSens Gardnerella vaginalis/Lactobacillus sp. QT PCR kit				
S3309B	eSens Mycobacterium tuberculosis/bovis/BCG QL PCR kit				
S3300A	eSens Bordetella pertussis/bronchiseptica/parapertussis QL PCR kit				
S3047A	eSens Florocenosis/Aerobes QT PCR kit				
S4301A	eSens MDR MBL QL PCR kit				
S4302A	eSens MDR KPC/OXA QL PCR kit				
S3006A	eSens Candida albicans QL PCR kit				
S3803B	eSens Pneumocystis jirovecii QL PCR kit				
S3041A	eSens Candida albicans/glabrata/krusei QL PCR kit				
S3804A	eSens Cryptococcus neoformans QL PCR kit				
S3046A	eSens Florocenosis/Candida QT PCR kit				
S3206A	eSens HHV6 QT PCR kit				
S3090A	eSens HPV LR 6/11 genotype QL PCR kit				
S3082A	eSens HPV HR 16/18 genotype QT PCR kit				
S3603B	eSens CCHFV QL PCR kit				
S3150B	eSens HGV QL PCR kit				
S3301B	eSens Influenza virus A H5N1 QL PCR kit				
S3201A	eSens HSV 1/2 genotype QL PCR kit				
S3100B	eSens HAV QL PCR kit				
S3540B	eSens Rotavirus/Norovirus/Astrovirus QL PCR k/c				
S3240A	eSens EBV/HHV6 QT PCR kit CMV F				
S3801B	eSens Parvovirus B19 QT PCR kit				
S3702A	eSens TBEV QL PCR Kit				

# eDetect Advanced PCR Diagnostic Line

- Our main and most advanced PCR diagnostic line
- First eDetect kits are to be launched in Q1-Q2/2026
- Developed and produced completely by Ecoli Dx
  - Our own chemistry
  - Raw materials with EU origin only (mainly CZ, DE)
  - Production in our facility absolute control over quality
    Improved warranty and support
    - Short lead times and responsiveness to specific demands
- All kits to be CE marked (EU) 2017/746 (IVDR)
  - RUO versions will also be available





## eDetect main features

**DOUBLE CONTROL OVER QUALITY** 

**EXO-IC**: internal exogenous control

**ENDO-IC: internal** endogenous control

#### **FAST AND CONVENIENT ASSAY SETUP**

Lyophylized polymerase

Provided in 2 separate tubes (2x25 reactions) – rehydrate them as you need

One-step preparation of the mastermix

> Hot Start polymerase temperature

# - assay setup at room

UDG enzyme to prevent carryover contamination from previous PCR runs

**PROTECTION** 

**AGAINST** 

**CONTAMINATION** 

In polymerase mix

#### **USE ANY REAL-TIME PCR INSTRUMENT**

Validated on CFX Opus 96 and RGQ

Can be used on other PCR instruments

> Any type of PCR plastic

#### **UNIFIED PCR THERMAL CYCLING PROTOCOLS**

You can combine different eDetect assays within one run



#### **ACCURATE SAMPLE QUANTIFICATION**

4 standards included in quantitative assays

> Easy-to-use quantification mixes



#### **CONVENIENT SHIPPING AND STORAGE**

Transport possible at room temperature

> Long shelflife (aiming for 24 months)





## eDetect menu

#### eDetect CT-NG QL PCR Kit – qualitative

- Chlamydia trachomatis (incl. Swedish New and Finnish Variant; sensitivity  $0.2 \pm 0.03$  cp/µl)
- Neisseria gonorrhoeae (sensitivity 0,2 ± 0,01 cp/µl)
- Sample type: DNA extracted from urogenital swabs urethral, vaginal) and urine (urine sediment)
- RUO version already available

#### eDetect CMV-EBV-HHV6 QT PCR Kit – quantitative

- Cytomegalovirus (sensitivity 143 IU/ml)
- Epstein-Barr virus (sensitivity 129 IU/ml)
- Human Herpesvirus 6 A,B (sensitivity 179 IU/ml)
- Sample type: DNA extracted from whole blood/plasma/serum

#### eDetect MG-MH-Uspp QL PCR Kit – qualitative

- Mycoplasma genitalium
- Mycoplasma hominis
- Ureaplasma species (U. parvum, U. urealiticum without differentiation)
- Sample type: DNA extracted from vaginal, urethral, rectal swab, urine (urine sediment), sperm, nasopharingeal (oral) swab, eye swab, LBC (e.g. PreservCyt)
- RUO version already available





eDetect Roadmap 2026/27

- HSV1-HSV2-VZV QT
- Toxoplasma gondii QL
- HSV-TV-TP QL
- IAV-IBV-SARSCoV2-RSV QL
- Hepatitis C virus QT
- Hepatitis B virus QT
- HBV-HCV-HIV1-HIV2 QL
- Other variations
  - Mono-plex kits
  - Different multiplex combinations





# Positioning of PCR kit brands

Customers who are fine with RUO

AmpliSens eDetect RUO

eSens (group D according to IVDR criteria)

Customers requesting CE IVD

eSens: legacy CE IVD-D

 Decided to take steps to meet the IVDR requirements for their continued marketing

eDetect: CE IVD-R

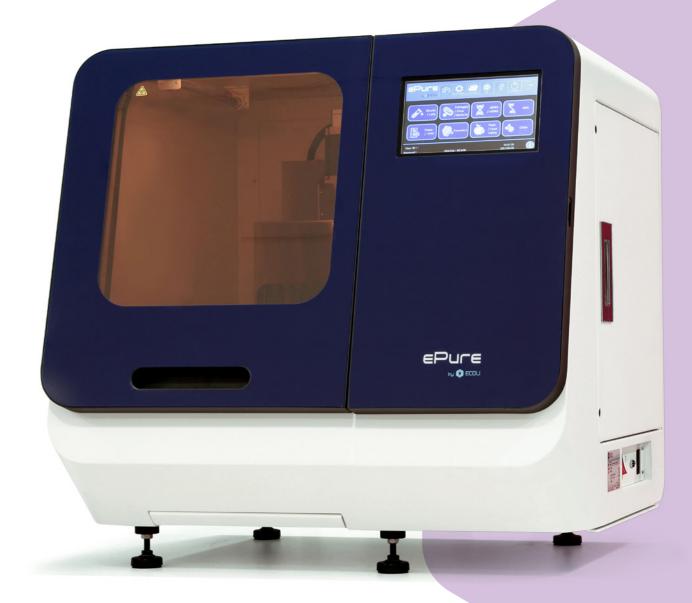
- Will be our main CE IVD solution along with the new instrumentation
- Main focus from our distributors expected



## **ePure**

## Fully automated nucleic acid extractor

- Liquid handling instrument based on magnetic particle extraction technology
- Purifies 1 to 12 samples simultaneously per run
- Compact bench-top design
- Built-in UV lamp decontamination
- Optimized in-built protocols
- Range of purification kits that contains all prefilled reagents and consumables







# ePure extraction kit menu

Cat.No.	Product name	Size	Description	Availability
E2001	ePure Blood DNA Extraction Kit	48 tests	extraction of genomic DNA from whole blood, buffy coat and leukocyte concentration	<b>√</b>
E2003	ePure Viral Nucleic Acid Extraction Kit	48 tests	extraction of viral DNA/RNA from serum, plasma or cell-free fluids	<b>✓</b>
E2004	ePure Tissue DNA Extraction Kit	48 tests	extraction of DNA from solid animal tissues, dried swab and dried blood	<b>√</b>
E2006	ePure Bacterial DNA Extraction Kit	48 tests	extraction of bacterial DNA from various sample types including environment material	<b>√</b>
E2007	ePure STD Extraction Kit	48 tests	extraction of nucleic acid from cervical swab and transfer medium	✓
E2008	ePure TB DNA Extraction Kit	48 tests	extraction of MTB DNA from various sample types (e.g. sputum, BAL, CSF, urine, blood)	on request
E2009	ePure FFPE DNA Extraction Kit	48 tests	extraction of genomic DNA from formalin-fixed, paraffin-embedded tissue (FFPE) samples	on request
E2010	ePure Forensic DNA Extraction Kit	48 tests	extraction of genomic DNA from a wide range of forensic & human identity samples	on request
E2014	ePure Plant DNA Extraction Kit	48 tests	extraction of genomic DNA from plant tissue and yeast	on request
E2015	ePure Total RNA Extraction Kit	48 tests	extraction of Total RNA from mammalian whole blood, human and animal tissues, cultured cells, plant tissue and yeast	on request







# eQuantix introduction

- 2 models
  - Capacity 32 tubes we have a prototype, launch in 6 months
  - Capacity 96 tubes launch in 15 months
- New technology of sample temperature ramp rate
  - Shortens run time roughly by 30 %
- High power LED, Detector: CMOS
- 5-channels: FAM/SYBR Green, HEX/JOE, ROX/TxR, Cy5, Cy5.5
- Laptop-like silent operation
- Open platform for any plastics/commercial kits
- Own user-friendly SW





# R&D projects

#### **eDetect**

- 2 applied for CE IVD-R certification
- 3 in later stage of development
- 45 CE IVD marked kits by 2029

## **eQuantix**

- 32-tube version in 6 months
- 96-tube version in 15 months

## Sample-To-Result Platform Gen1

OEM, similar technology to ePure, in 12 months

## Sample-To-Result Platform Gen2

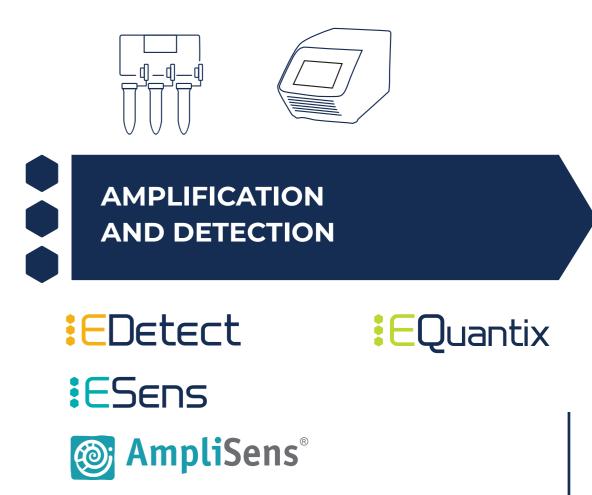
- Integration of our own extraction technology eQuantix technology
- In development

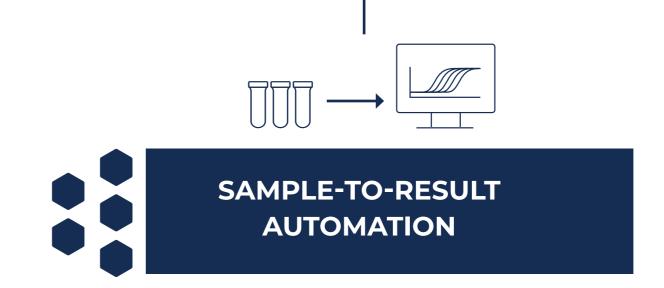




# Complete solution for PCR diagnostics of infectious diseases from A to Z







Support of our distributors

## **Scientific & Technical Support**

- Helpful tech-support team
- Trainings
  - Application and service/hardware Online or at our facility near Prague
- Extensive resources on our web

### **Regulatory & Documentation Assistance**

- Helpful sales & regulatory team
- Extensive resources on our web

### **Logistic & Operational Support**

- Reliable order and shipping processing
- Support with import/customs documentation

## **Business Development Support**

- Joint participation in exhibitions or conferences
- Lead sharing (inquiries from your territory)





# 3 points of contact

## Logistics

ecolidx@ecolidx.com

For orders and requests for availability, delivery terms and shipping, product documentation

## **Tech support**

techsupport@ecolidx.com

Pre-sale and post-sale technical questions on products, application support, technical claims, hardware issues

#### Sales

tomas.vydareny@ecolidx.com

Anything that helps you grow Requests for special pricing, product registrations, trainings, contracts, authorization letters, events Business planning







