

EKF Diagnostics Holdings plc
("EKF", the "Company" or the "Group")

Strategic partnership agreement with Yourgene Health plc

Collaboration to broaden testing capabilities through EKF's accredited US laboratory beyond COVID-19

EKF Diagnostics Holdings plc (AIM: EKF), the AIM-listed point-of-care business, has signed a strategic partnership agreement with Yourgene Health plc ("Yourgene", AIM: YGEN), a leading international molecular diagnostics group, whereby EKF will offer a non-invasive prenatal test ("NIPT") service to the US market based on Yourgene's proprietary Flex technology, using EKF's accredited US laboratory to process returned test samples. Over time, EKF and Yourgene intend to provide further tests including in oncology, for which Yourgene has additional tests. The agreement is for an initial 5-year period.

EKF's facilities are those of Advanced Diagnostic Laboratory LLC ("ADL Health"), a recently acquired Texas based testing laboratory certified under the Clinical Laboratory Improvement Amendments ("CLIA") for high complexity testing. ADL Health has the in-house testing capabilities to broaden its diagnostics offering from its current range of rapid and accurate COVID-19 testing services into the expanding market of NIPT, amongst other areas. This partnership with Yourgene enables EKF to follow its strategy to grow its CLIA laboratory business beyond COVID.

As part of the agreement, EKF will purchase state-of-the-art next generation sequencing ("NGS") technology ("Illumina NextSeq 550") and Yourgene's proprietary technology, to enable ADL to build NIPT screening services for a wide range of clinical conditions across reproductive health (including Down's Syndrome and other genetic disorders). It also provides the opportunity to use NGS technology independently to extend EKF's testing capabilities into other areas such as cardiovascular disease testing (designed to determine the genetic predisposition towards cardiomyopathy, hypercholestermia, and other risk factors), hereditary cancer risk, genetic predisposition for Alzheimer's disease, Parkinson's disease and dementia.

The adoption for NIPT in the US has accelerated with recent guidelines issued from American College of Obstetricians and Gynaecologists ("ACOG") recommending NIPT to be made available to all pregnant women¹. As part of the agreement, Yourgene will provide ADL Health with access to YGEN's proprietary reagents and NGS analysis software as part of a technology transfer agreement to enable ADL Health to build a rapid turnaround NIPT service for the US market. Currently, a majority of US NIPT samples are sent to large central testing laboratories, which are costly and experience lengthy lead times. In contrast, the new ADL NIPT service will offer rapid turnaround times as the NIPT workflow can be performed in as little as 48 hours,

enabling a competitive response and allowing both EKF and Yourgene to gain traction in this large growing market. According to third party forecasts, the US NIPT market is expected to reach a valuation of USD 2.5 Billion by 2028².

Within the collaboration Yourgene will also provide ADL Health a range of YGEN's additional PCR portfolio for screening Cystic Fibrosis, rapid aneuploidy assay and DPYD (chemotherapy toxicity) tests, creating a wider range of products for use in reproductive health and oncology.

Mike Salter, Chief Executive Officer, commented: *"We are extremely pleased to have formed this partnership with Yourgene, allowing EKF to offer NIPT and oncology tests as part of its proposed strategy of expanding its CLIA laboratory testing portfolio beyond COVID-19 assays. We are thrilled to be growing our reach further within the largest healthcare market in the world and look forward to working with Yourgene going forward."*

Lyn Rees, Chief Executive Officer of Yourgene, commented: *"We are thrilled to have entered into this collaboration with EKF and ADL Health, a well-established group in the US with a large clinical network of customers positioned to increase uptake of the tests. This partnership is testament to the strength of our technical capabilities and accelerates our US growth plans to broaden our portfolio in the region with strategic partners. I am excited to be working with EKF and this partnership is a great platform for growth within the largest healthcare market in the world."*

- 1 ACOG Practice Bulletin No. 226. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2020;136:e48-69), summarised at <https://www.acog.org/advocacy/policy-priorities/non-invasive-prenatal-testing>
- 2 www.researchandmarkets.com/reports/5354677/u-s-non-invasive-prenatal-testing-market

EKF Diagnostics Holdings plc
Christopher Mills, Non-executive Chairman
Mike Salter, CEO
Marc Davies, CFO

www.ekfdiagnostics.com
Tel: +44 (0)29 2071 0570

Singer Capital Markets (Nominated Adviser & Joint Broker)
Aubrey Powell / George Tzimas / Tom Salvesen

Tel: +44 (0)20 7496 3000

Investec Bank plc (Joint Broker)
Gary Clarence / Daniel Adams

Tel: +44 (0)20 7597 4000

Walbrook PR Limited
Paul McManus / Lianne Applegarth

Tel: +44 (0)20 7933 8780 or ekf@walbrookpr.com
Mob: +44 (0)7980 541 893 / +44 (0)7584 391 303

About EKF Diagnostics Holdings plc (www.ekfdiagnostics.com)

EKF is a leading point-of-care diagnostics and central laboratory assay manufacturer with an estimated 80,000 hemoglobin, hematocrit, HbA1c, glucose and lactate

analysers in regular use across more than 100 countries. EKF specialises in developing tests for use in anemia and diabetes diagnosis and management, as well as providing a portfolio of reagents for use in clinical chemistry analysers.

EKF specialises in the development, production and worldwide distribution of point-of-care analyzers and clinical chemistry reagents for use in hospital and research laboratories, doctor's offices, blood banks and for in-field anaemia screening programmes. EKF is also a bulk manufacturer of enzymes and has custom manufacturing facilities across sites in the US, UK and Europe for a variety of life science products. Driven by customer demand EKF has invested significantly in increasing the Company's fermentation capacity. The Company's capabilities and capacity in contract manufacturing for sample collection, tests and test kits have seen dramatic growth following strong demand for during the COVID-19 pandemic, and these income streams are now being diversified for application to other non-COVID areas of diagnostic testing, molecular disease and forensic test manufacture.

In May 2021, EKF outlined its strategy through to 2024 for delivering additional growth. As well as the growth expected in Contract Manufacturing across Life Sciences, molecular diagnostics and other applications, the Company expects to leverage existing distribution channels for organic growth, both in the core business and from additional products to expand the core range, but also through executing earnings enhancing acquisitions and delivering further value creating investments associated with the preferred partnership agreement with Mount Sinai Innovation Partners.

In October 2021, EKF completed the acquisition of Advanced Diagnostic Laboratory LLC, a Texas based testing laboratory certified under the Clinical Laboratory Improvement Amendments ("CLIA") for high complexity testing. The laboratory provides testing for a variety of clinical, forensic and microbiological sample types using a range of analytical techniques. This acquisition positions EKF as a leading 'one stop' provider of diagnostic products and services from sample collection to results.

This information is provided by Reach, the non-regulatory press release distribution service of RNS, part of the London Stock Exchange. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lse.com or visit www.rns.com.

Reach is a non-regulatory news service. By using this service an issuer is confirming that the information contained within this announcement is of a non-regulatory nature. Reach announcements are identified with an orange label and the word "Reach" in the source column of the News Explorer pages of London Stock Exchange's website so that they are distinguished from the RNS UK regulatory service. Other vendors subscribing for Reach press releases may use a different method to distinguish Reach announcements from UK regulatory news.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock

Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

NRALDLLFLFLFBBB admin Strategic partnership agreement with Yourgene 32397487 A Tue,
01/18/2022 - 07:01 LSE RNS Company Announcement - General EKF