



Diagnostics for life

# EKF Diagnostics Holdings plc

Results for the year ended 31 December 2020

30 March 2021

[ekfdiagnostics.com](https://ekfdiagnostics.com)

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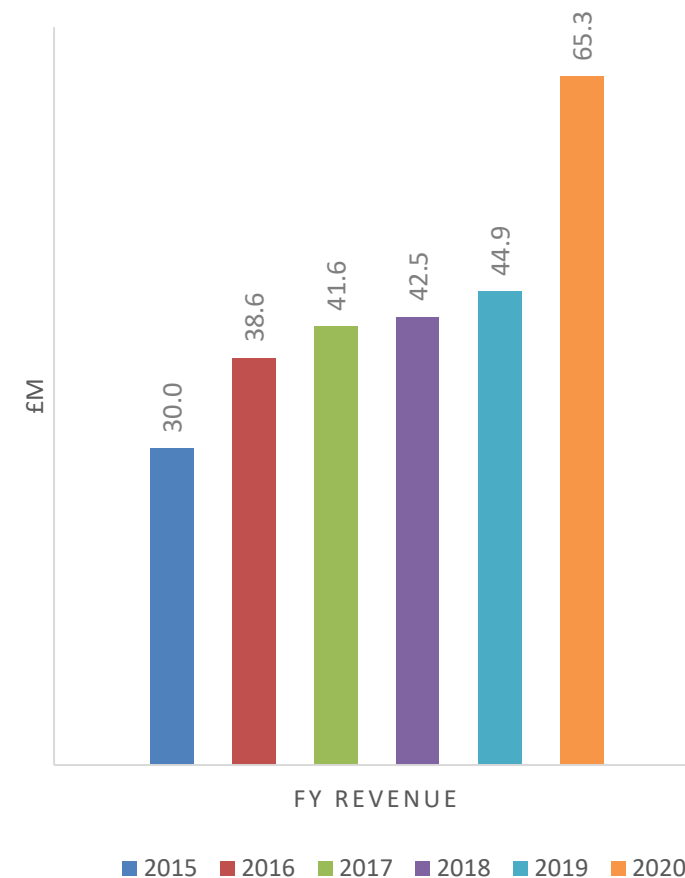
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# Agenda

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# Financial highlights

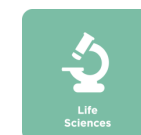
- ▶ Revenues up 45% to £65.3m (2019: £44.9m)
  - DiaSpect Tm up £548k (15%)
  - Quo-Lab up £210k (9%)
  - Contract manufacturing up from £175k to £26.3m
- ▶ Gross profit up 58% to £37.4m (2019: £23.7m)
- ▶ Adjusted EBITDA<sup>1</sup> up 113% to £25.5m (2019: £12.0m)
- ▶ Profit before £15.4m (2019: £5.5m)
- ▶ Basic Earnings per share of 2.45p (2019: 0.81p)
- ▶ Cash generated from operations £13.8m (2019: £5.1m)
- ▶ Cash at 31 December 2020 £21.9m (2019: £12.1m), net cash after borrowings of £21.4m (2019: £11.4m)
- ▶ Value of investments in marketable securities at year end of £6.5m, after sales of Renalytix shares raised £7.7m (2019: £9.7m)
- ▶ Maiden cash dividend paid to shareholders of 1p per ordinary share



<sup>1</sup> Earnings before interest, tax, depreciation and amortisation, share-based payments and exceptional items, as laid out in the income statement

# Operational highlights

- ▶ Significant improvements in revenue and profit, resulting from successful COVID-19 related contract manufacturing business
- ▶ Core business held up well. Revenues down £6.5m YoY (-14%) however there were strong performances and signs of a steady recovery are apparent:
  - DiaSpect Tm up £548k (15%) due to strong performance from OEM partners McKesson and Fresenius Kabi
  - Quo-Lab up £210k (9%) due to improved sales in EMEA and improved shelf-life of reagent cartridges
  - Hemo Control and HemoPoint H2 sales down £2.6m (-36%) as anaemia screening programmes were paused or cancelled, particularly Peru (-£1.1m), and reduced demand from Women & Infants Clinics in US
  - $\beta$ -HB down £847k (-9%) due in part to the fulfilment of large orders from Cardinal in Q4 2019
  - Reduced demand for diabetes testing, especially in China and south east Asia
  - COVID-19 restrictions in laboratories, universities and organized sport impacted research use market for lactate and clinical chemistry products
- ▶ Post period end, recovery of core business underway in Q1 2021:
  - Fresenius Kabi up 20% YoY following tender wins in Asia and the Middle East
  - Tender win in Rwanda c. 200k tests; screening programmes in Uganda, Ghana, Kenya and Egypt
  - First shipment of 1,000 DiaSpect Tm analysers to South Africa following tender win
  - CBER<sup>1</sup> approval of DiaSpect Tm allows EKF to start selling into US blood banks from March 2021
  - Won South Carolina WIC<sup>2</sup> tender, displacing HemoCue. Other WIC tender opportunities expected
  - New pregnancy testing accounts won following exit of major competitor from the US market
  - Won Jharkhand (India) tender (3 million DiaSpect Tm cuvettes). Additional tenders in the pipeline



# Contract manufacturing upscaled in response to COVID-19

- ▶ Existing relationship with Longhorn Vaccines & Diagnostics, based in San Antonio
  - c. 20,000 tubes of PrimeStore MTM sold in 2019
  - 2019 revenue: £44,095
- ▶ Demand for PrimeStore MTM increased exponentially in Q2 2020 in US
  - Filled and capped tubes
  - Over 50,000 litres of PrimeStore MTM medium made at Boerne site and transported to third party fulfilment sites
  - Manufacturing lines for PrimeStore MTM established in Elkhart and South Bend (both Indiana, US)
- ▶ Public Health England evaluation of PrimeStore MTM published September 2020
  - Supply contracts won with Public Health England, private labs and universities in the UK
  - Large contract with distributor to supply the Government of Ireland
  - Exports to European mainland following business wins in Germany and with multi-national partner
  - Manufacturing lines established in Cardiff, Barleben and Leipzig
- ▶ £26.3 m in revenue globally in 2020 from PrimeStore MTM
- ▶ c. 2 million tubes of PrimeStore MTM sold across all manufacturing sites
- ▶ Additional production lines for Phosphate Buffered Saline (PBS) established Q1 2021 at Boerne, South Bend, Barleben and Cardiff sites



# Life Sciences

- ▶ Overall core business from customers such as Roche continued with minor loss of business
- ▶ Oragenics: Business continued more slowly as their focus switched from the lantibiotic to the COVID vaccine. Despite this progress was achieved:
  - Scale-up development phase starting Q3 2022 onwards on the C.diff. lantibiotic
  - Other projects are in the pipeline
  - Contract manufacturing work to restart in Q3 2021
- ▶ Ixcela: Development process finished, manufacture of end-product starting mid Q3 2021
- ▶ iGenomics: Project experienced several delays including the redesign of the clone, which is now working well
- ▶ New account wins including Stepan, Purissima, ArcBio and Simpleseq
- ▶ Slowed capex spend to match the progress of Life Science projects. Management expects expenditure to increase as projects come back online:
  - Facilities expected to be complete in 24 months, although demand may necessitate early completion (within 15-18 months)
- ▶ The cannabidiol market is driving a lot of the anticipated market growth, predicted to increase from \$2.8 bn at a CAGR of 52.7% from 2020-2026

ORAGENICS

IXCELA  
The Internal Fitness™ Company

iGENOMIX



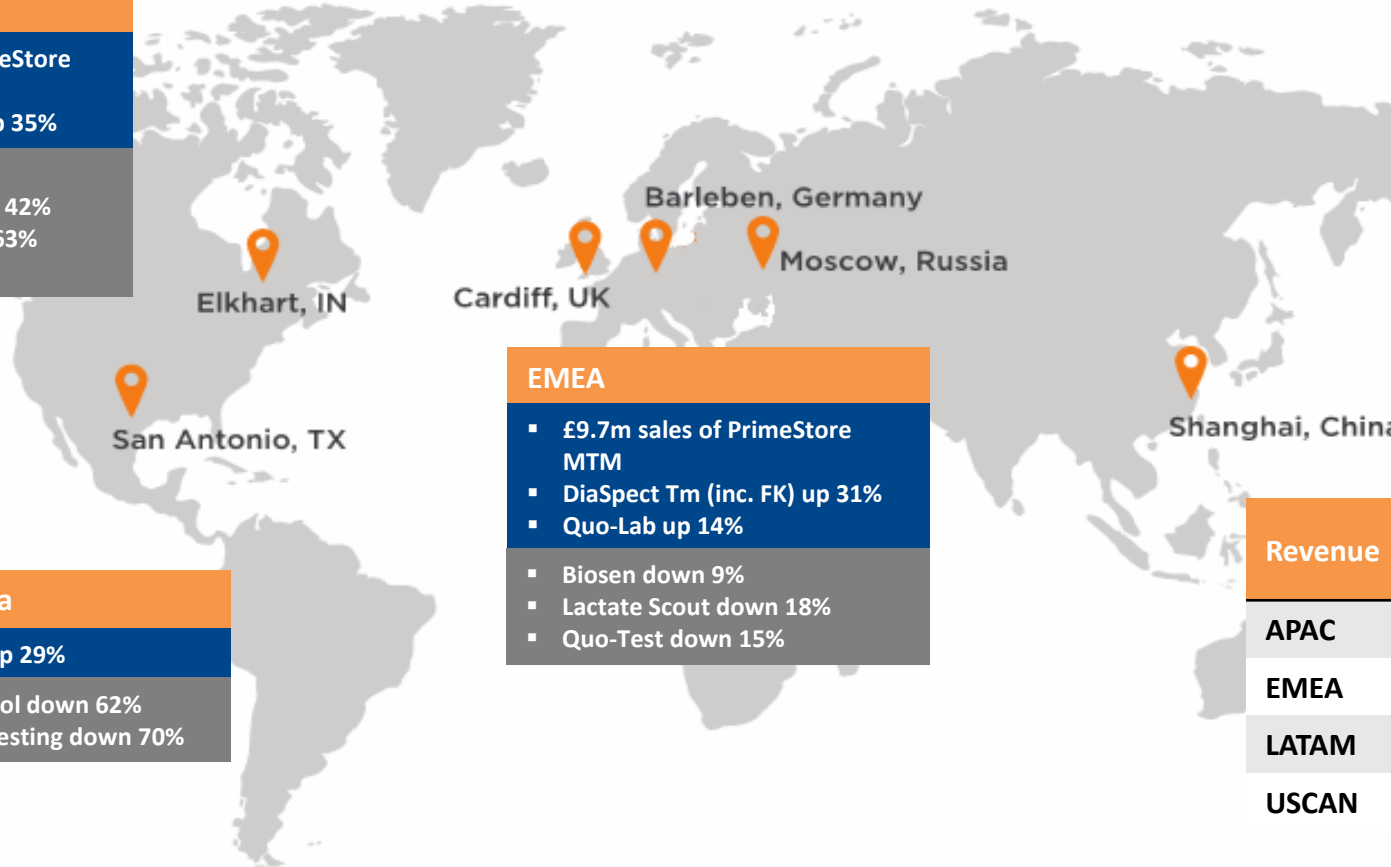
# Global revenue breakdown

## USA & Canada

- £15.9m sales of PrimeStore MTM
- McKesson Consult up 35%
- $\beta$ -HB down 9%
- HemoPoint H2 down 42%
- Lactate Scout down 63%
- UltraCrit down 39%

## APAC

- Biosen up 21%
- Quo-Lab up 3%
- Chemistry down 11%
- DiaSpect Tm down 37%
- Quo-Test down 50%



## Latin America

- Chemistry up 29%
- Hemo Control down 62%
- Pregnancy testing down 70%

## EMEA

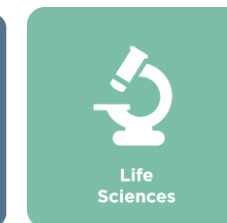
- £9.7m sales of PrimeStore MTM
- DiaSpect Tm (inc. FK) up 31%
- Quo-Lab up 14%
- Biosen down 9%
- Lactate Scout down 18%
- Quo-Test down 15%

Revenue	FY 2020 £k	FY 2019 £k	+/- £k
APAC	3,747	4,509	(762)
EMEA	24,339	14,881	9,458
LATAM	2,050	3,632	(1,582)
USCAN	35,112	21,894	13,218



# Central Laboratory & Life Sciences FY 2020

Clinical chemistry, lab analysers, contract fermentation and enzymes



- ▶ Revenues up £24.9m (405%) to £31m
- ▶ Contract manufacturing up from £175k to £26.3m
  - PrimeStore MTM tube and bulk liquid manufacturing
  - PBS solution introduced into market Q4 2020 as a low cost alternative to MTM
  - Manufacturing operations in five locations: Boerne, South Bend, Barleben, Leipzig and Cardiff
  - Supply contracts with Public Health England, Government of Ireland, universities, private labs and blue-chip industrial partners
- ▶ Agreement with two reference labs to add Glycated Albumin to their portfolio
- ▶ Contract manufacturing opportunities impacted due to the demand on facilities created by PrimeStore MTM in US

**Central Lab & Life Sciences**

PrimeStore MTM  
 Clinical chemistry  
 Small lab analysers  
 Contract fermentation  
 Enzyme manufacturing



	FY 2020 £k	FY 2019 £k	+/- £k	+/- %
Central Laboratory (inc. chemistry, Altair, GA)	2,720	3,234	(514)	(16%)
Contract Manufacturing	26,316	175	26,141	14,938%
Life Sciences	1,959	2,725	(766)	(28%)
<b>Total</b>	<b>30,995</b>	<b>6,135</b>	<b>24,860</b>	




# Diabetes FY 2020



- ▶ Revenues down £1,551k (-7.5%)
- ▶ Quo-Lab up £210k (9%)
  - 24% growth in sales of reagents in EMEA markets
- ▶ STAT-Site β-HB and STAT-Site WB up £39k (2%)
- ▶ β-HB LiquiColor reagent down £847k (9%)
  - Sales in 2020 impacted by the fulfilment very high stocking order made by Cardinal in December 2019
- ▶ Quo-Test down £614k (-25%)
  - Drop primarily attributed to reduced testing at diabetes clinics globally during national lockdowns
  - Growth in Germany (up 5.2% YoY)
- ▶ Biosen down £339k (-7%)
  - Lower demand for consumables in China and Russia during lockdowns

**Diabetes range**

- Biosen C-Line
- Quo-Lab A1c
- Quo-Test A1c
- STAT-Site WB
- STAT-Site β-HB
- β-HB LiquiColor



	2020 £k	2019 £k	+/- £k	+/- %
Diabetes analysers and tests	19,056	20,607	(1,551)	(7.5%)



# Hematology FY 2020



- Revenues down £2,771k (-20%)
- DiaSpect Tm up £548k (15%)
  - Strong performances from McKesson and Fresenius OEM agreements
  - Kenyan tender c. 2m tests
  - Won first blood bank tender in Scotland c. 400k tests
- Hemo Control and HemoPoint H2 down £2,652k (-36%)
  - Sales down £1.1m to Peru as screening programmes halted due to COVID-19
  - McKesson switch to DiaSpect Tm OEM (Consult) and reduced demand reduced sales by £500k
  - Closure of US WIC centres during pandemic to reduce transmission of disease to vulnerable people and health workers reduced sales by £700k
  - Global reduction in blood donations

## Hematology range

DiaSpect Tm  
HemataStat II  
Hemo Control  
HemoPoint H2  
UltraCrit



	2020 £k	2019 £k	+/- £k	+/- %
Hematology analysers and tests	11,037	13,808	(2,771)	(20%)

# Commercial partnerships

- ▶ Preferred partnership agreement with Mount Sinai Innovation Partners (MSIP), NYC (Sept. 2019)
  - Agreement provides EKF with advanced access to innovative commercial opportunities arising from Mount Sinai Health System (MSHS) owned technologies managed by MSIP in the field of digital healthcare
- ▶ \$5m investment in Trellus Health for c. 31% share of business announced 20 August 2020  
Trellus to develop a resilience-driven digital health solution for complex chronic conditions
  - Multi-year licence with MSHS to commercialise Trellus' GRITT-IBD resilience assessment and personalised treatment methodology
  - Focused on the treatment of chronic conditions, starting with Inflammatory Bowel Disease (IBD), including Crohn's disease and ulcerative colitis
  - 90% of the US \$3.3 trillion annual health care expenditure is for chronic diseases with patients suffering from both chronic medical and mental health conditions costing twice as much (Centers for Disease Control & Prevention, CDC)
  - Intention to IPO Trellus on AIM in H1 2021; EKF's holding distributed in specie to our shareholders in December 2020
- ▶ Remaining holding in RenalytixAI valued at £4.9m (at 31 December 2020) (book value at cost: £1.2m)
  - EKF sold 1,675,000 shares for £7.7m in November 2020 (vs. cost of £2.0m)
  - 1,002,981 shares remaining
- ▶ Verici Dx PLC (formerly 'Fractal Dx') spun-out from RenalytixAI
  - Formed to enable the accelerated development of its portfolio of transplant diagnostic and prognostic products and the achievement of commercial milestones
  - RenalytixAI holders at 9 July 2020, including EKF, received one Verici A share in specie for each ordinary share held in Renalytix AI. EKF beneficial holding is 2,677,981 ordinary shares in Verici. Lock-up period of 365 days following admission on 6 November 2020
  - Holding of 2,677,981 shares with a value of £1.6m at 31 December 2020



# 2021 Outlook

- ▶ The Board is confident that trading for the year ending 31 December 2021 will be significantly ahead of already upgraded management expectations throughout 2021
  - 30 March 2021 announced the signing of a multi-million dollar global supply contract with a private sector partner
  - Core business experiencing a strong recovery, particularly in the US
- ▶ McKesson OEM of DiaSpect Tm expected to return to pre-pandemic sales expectations
  - Customer base intact but was impacted by closure of physicians' offices to medical sales representatives throughout 2020
  - Placement of analysers into setting expected to return to 2020 levels (c. 100 per month) during 2021
- ▶ Continued demand for PrimeStore MTM tubes and bulk medium
  - £2.49m of orders to Ireland in Q1 (versus £5.2m in 2020)
  - £3m+ of orders in-house from Concepta, Oncologica and PHE Manchester
- ▶ Orders of PBS (phosphate-buffered saline) to exceed £2.4m in Q1
  - Two-year global supply contract with a major international brand customer for regular staff testing and home-use
  - Manufactured at sites in the US, UK and Germany
- ▶ Trellus Health flotation expected in H1 2021 to generate further value for holders

Appendix  
**Financial report**

# Consolidated Income Statement (Extract)

	FY 2020 £k	FY 2019 £k	+/- £k
Revenue	65,260	44,917	20,343
Gross profit	37,420	23,727	13,693
GM %	57%	53%	4%
Administrative expenses	(20,658)	(18,280)	(2,378)
Other income	133	337	(204)
<b>EBITDA</b>	<b>25,516</b>	<b>12,005</b>	<b>13,511</b>
Share based payments	(5,292)	(2,118)	(3,174)
Exceptional items	1,282	338	944
Depreciation / amortisation	(4,611)	(4,441)	(170)
Finance costs / income	(1,539)	(266)	(1,273)
Income tax charge	(3,971)	(1,586)	(2,385)
<b>Profit for the year</b>	<b>11,385</b>	<b>3,932</b>	<b>7,453</b>

# Consolidated Balance Sheet (Extract)

	FY 2020 £k	FY 2019 £k	+/- £k
Property, plant, equipment	12,620	12,179	441
Intangible assets	37,051	37,767	(716)
Inventories	8,487	6,073	2,414
Trade / other receivables	13,553	8,097	5,456
Cash and cash equivalents	21,913	12,074	9,839
Trade / other payables	14,435	7,470	6,965
Borrowings	508	655	(147)



# Balance Sheet: Assets at 31 December 2020

	Selected items	FY 2020 £k	FY 2019 £k	+/- £k
<b>Non-current assets</b>	Property, plant, equipment	12,620	12,179	441
	Right-of-use assets	1,019	1,002	17
	Intangible assets	37,051	37,767	(716)
	Investments	6,608	9,900	(3,292)
	Deferred tax assets	14	34	(20)
	<b>Total non-current assets</b>	<b>57,312</b>	<b>60,882</b>	<b>(3,570)</b>
<b>Current assets</b>	Inventories	8,487	6,073	2,414
	Trade and other receivables	13,553	8,097	5,456
	Deferred tax assets	14	34	(20)
	Cash and cash equivalents	21,913	12,074	9,839
	<b>Total current assets</b>	<b>43,953</b>	<b>26,244</b>	<b>17,709</b>
<b>Assets</b>	<b>Total assets</b>	<b>101,265</b>	<b>87,126</b>	<b>14,139</b>

# Balance Sheet: Equity and Liabilities at 31 December 2020

Selected items		FY 2020 £k	FY 2019 £k	+/- £k
<b>Total equity</b>		<b>78,200</b>	<b>71,172</b>	<b>7,028</b>
<b>Total non-current liabilities</b>		<b>3,649</b>	<b>3,099</b>	<b>550</b>
<b>Current liabilities</b>	Trade and other payables	14,435	7,470	6,965
	Lease liabilities	380	286	94
	Deferred consideration	2,901	1,385	1,516
	Current income tax liabilities	1,515	2,823	(1,308)
	Deferred tax liabilities	2,636	2,619	17
	Borrowings	185	175	10
<b>Total current liabilities</b>		<b>19,416</b>	<b>12,139</b>	<b>7,277</b>
<b>Total liabilities</b>		<b>23,065</b>	<b>15,954</b>	<b>7,111</b>
<b>Total equity and liabilities</b>		<b>101,265</b>	<b>87,126</b>	<b>14,139</b>

# Cash Flow

	FY 2020 £k	FY 2019 £k	+/- £k
<b>Net cash generated by operating activities</b>	<b>13,809</b>	<b>5,100</b>	<b>8,709</b>
Net cash generated by /(used) in investing activities	1,336	(2,396)	3,732
Net cash used in financing activities	(5,209)	(634)	(4,575)
<b>Net increase in cash and cash equivalents</b>	<b>9,936</b>	<b>2,070</b>	<b>7,866</b>
Exchange (losses)/gains on cash and cash equivalents	(97)	(278)	181
<b>Cash and cash equivalents at end of year</b>	<b>21,913</b>	<b>12,074</b>	<b>9,839</b>

**Thanks  
for your attention**